HEALTH EFFECTS OF SMOKELESS TOBACCO

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON
ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

NOVEMBER 29, 1994

Serial No. 103–163

Printed for the use of the Committee on Energy and Commerce

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CONTENTS

Page

Testimony of:
- Bender, Rick, oral cancer survivor 119
- Connolly, Gregory N., Director, Massachusetts Tobacco Control Program, on behalf of the Coalition on Smoking and Health 49
- Cooper, Jeff, head athletic trainer, Philadelphia Phillies 118
- Eriksen, Michael P., Director, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention 33
- Garagiola, Joe, Chairman, National Spit Tobacco Education Program 115
- Henningfield, Jack, Chief, Clinical Pharmacology Branch, Addiction Research Center, National Institute on Drug Abuse 41

Material submitted for the record by:
- American Fund for Dental Health, statement of 126
- Health and Human Services, Department of, factsheet 131
- Indiana University, letter dated November 23, 1994, regarding smokeless tobacco studies 128
- Oregon Research Institute, letter dated November 28, 1994, research and clinical experience 130
- Minnesota, University of, letter dated November 23, 1994, research on smokeless tobacco 129
- National Institute on Drug Abuse, letter dated December 13, 1994, answers to followup questions to Mr. Henningfield 111
- Robert C. Byrd Health Sciences Center, letter dated November 22, 1994 from Elbert Glover to Chairman Waxman, research on smokeless tobacco 105
- U.S. Tobacco Company, response to letter dated May 19, 1994, from Hon. Henry A. Waxman 134

HEALTH EFFECTS OF SMOKELESS TOBACCO

TUESDAY, NOVEMBER 29, 1994

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 11:06 a.m., in room 2322, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. The meeting of the subcommittee will come to order.

This Congress, we have conducted a series of 10 hearings on tobacco products. We have covered a wide range of topics from the health effects of secondhand smoke to secret industry research on the dangers of smoking, to the addictiveness of tobacco. We have gained valuable and often dramatic new insights into the tobacco industry, and we have raised many questions that deserve future investigation. One of the most important issues raised during these hearings has been the role of nicotine in tobacco.

In March, the FDA commissioner, Dr. David Kessler, told us that nicotine is the addictive ingredient in tobacco. In April, two industry scientists, Dr. Victor DeNoble and Paul Mele, described to us their previously secret research to determine nicotine's exact addiction potential and to find nicotine analogues. And in June, we released dozens of studies by the Brown & Williamson Tobacco Company detailing the tobacco industry's intimate understanding acquired over a 30-year period of the pharmacological properties of nicotine.

We have also heard startling testimony about the tobacco industry's efforts to manipulate nicotine, including Dr. Kessler's testimony that the Brown & Williamson Tobacco Company bred a secret strain of tobacco, code named Y-1, that was supercharged with nicotine.

Today's hearing is again about nicotine; this time in smokeless spit tobacco. Specifically, the hearing is about whether the makers of smokeless tobacco deliberately manipulate nicotine to hook users. The manipulation of nicotine in smokeless tobacco is a vital public health concern because of the product's growing use among children.

Allegations of nicotine manipulation in smokeless tobacco first came to the subcommittee's attention on March 25, when Dr. Kessler presented information that smokeless tobacco products with lower amounts of nicotine are marketed as starter products for new users and that advertising is used then to encourage users

to graduate to products with higher nicotine levels. On April 14, these allegations of nicotine manipulation and the use of a graduation strategy were denied by Joseph Taddeo, the chief executive officer of U.S. Tobacco, when he appeared before our committee. U.S. Tobacco is the Nation's largest manufacturer of smokeless tobacco.

On October 26, further information about nicotine manipulation and the use of graduation strategies emerged in an article published in the Wall Street Journal. In this article, former employees of U.S. Tobacco described how the company added chemicals to its product to raise the pH level of the tobacco and thereby increase the amount of nicotine ingested by the user. These allegations raised important questions about the veracity of Mr. Taddeo's testimony before the subcommittee. The subcommittee called this hearing to give Mr. Taddeo a chance to respond to the Wall Street Journal article. The subcommittee also requested that U.S. Tobacco Company waive the confidentiality agreement with respect to an important former employee quoted in the Journal article.

Unfortunately, Mr. Taddeo declined to appear before us today or to waive the confidentiality which would allow other witnesses to testify. Despite the refusal of U.S. Tobacco to appear, we have decided to go ahead with this hearing because of the importance of the new information to be presented.

From the testimony of the first panel, we will learn that chemical analyses of smokeless tobacco show clear evidence of nicotine manipulation, and we will also consider documents that describe U.S. Tobacco's graduation strategy. And in the second panel we will hear compelling firsthand accounts from professional athletes about the dangers and addictiveness of smokeless tobacco.

This hearing will not provide final answers to the role of nicotine in smokeless tobacco. Final answers require more investigation and the opportunity to question Mr. Taddeo and former key employees, none of which is possible in the limited time remaining in this Congress. But this hearing will be important to bring new information to light, help the American people to understand the dangers of smokeless tobacco, and perhaps most important of all, raise the questions that need to be answered in future investigations.

I want to call on Members of the subcommittee for opening comments before we recognize our witnesses and receive their testimony. And I want to call on first Mr. McMillan.

Mr. MCMILLAN. Thank you, Mr. Chairman. I feel like a prize fighter after a long career of some 45 fights and this is my last fight in the 15th round, and I look forward to a different profession. Perhaps you do as well, Mr. Chairman.

Mr. WAXMAN. Let me say before you go on, that you and I have disagreements about issues now and then, maybe more often than not, but I think we are going to sorely miss you because of the integrity in which you served and the diligence in which you tried to address these tough issues, and the way in which you have always handled these agreements and disagreements. I am sorry to see you go and I wish you the very best in whatever you plan to do in the future. I plan to be here for 2 years, but certainly in a very different capacity.

Mr. MCMILLAN. Well, I want to wish you the best. And I share the mutual respect I think that we enjoy, even though we do dis-

agree from time to time. I think we have done so in a constructive manner. And I hope you will continue to be constructive, under a different set of circumstances. I am sure you will.

I wanted to comment a little bit on the nature of this hearing today and set the record straight in terms of what I think is a little bit of a distortion. Mr. Chairman, in your letter to Mr. Taddeo dated April 18, 10 days ago, you stated that this hearing was prompted by a recent article in the Wall Street Journal which you stated raised, "raised serious questions," about U.S. Tobacco Company and Mr. Taddeo's previous testimony. And I think you repeated that in your opening statement. Based on affidavits by two former employees of U.S. Tobacco, James Taft and Larry Story, I believe that this hearing should be directed to the credibility of the newspaper article you cited, rather than the credibility of Mr. Taddeo.

Mr. Chairman, the newspaper article referred to made the very serious allegation that U.S. Tobacco, "manipulates the amount of nicotine that users absorb," and that therefore U.S. Tobacco, "doctors," its smokeless products. The article cited the two former U.S. Tobacco chemists that I mentioned as the basis for these allegations and stated that, "their descriptions provide powerful support for allegations that the tobacco industry has spiked products to boost nicotine delivery." The very charge, incidentally, made by Dr. Kessler, or perhaps not incidentally.

Mr. Chairman, what troubles me is that this rather hastily convened hearing is based on a newspaper article which the two chemists themselves quoted in the article, or at least misquoted in the article, have stated in sworn affidavits is false and misleading. Let me quote pertinent paragraphs from affidavits that I will ask to be made a part of the record at the conclusion of our opening statement.

Mr. Taft, in his statement, says specifically I did not tell Ms. Freedman, she wrote the article, nor do I believe that U.S. Tobacco Company ever manipulated pH levels for the purpose of increasing free nicotine. I disagree with the thesis of the article that U.S. Tobacco Company doctors its smokeless brands to manipulate the amount of nicotine that users absorb.

In paragraph four of his affidavit, my experience at U.S. Tobacco Company was that products were developed according to taste preferences of consumers. Achievement of certain free nicotine levels was never discussed as part of the product development process.

Paragraph five, in sum, I am sure that what I told Ms. Freedman did not constitute any support for the allegations that U.S. Tobacco Company has, "spiked products to boost nicotine delivery." And pertinent quotes from another affidavit of Larry Story, who was cited in the article, who stated in his affidavit in paragraph one, in fact to my knowledge U.S. Tobacco Company did not manipulate pH levels in its products for nicotine related reasons.

Paragraph four, I understand U.S. Tobacco Company has added certain ingredients to its products according to age-old formulas derived long before free nicotine was an issue. This process related to taste-related reasons not having to do with free nicotine.

In paragraph five, while I recall that different U.S. Tobacco Company products contain different levels of nicotine, I do not believe

that, as suggested by the article, that U.S. Tobacco Company, "each product at U.S. Tobacco Company," "each product occupied a specific rung on the nicotine absorption ladder."

And in paragraph six, I am certain that what I told Ms. Freedman does not constitute what the article called, "powerful support for allegations that the tobacco industry has spiked products to boost nicotine delivery."

Mr. Chairman, I think these affidavits suggest that perhaps Mr. Taddeo and U.S. Tobacco have already been tried and convicted to some degree by the press article, with little consideration for the actual facts. And therefore, I request that an affidavit of Mr. James Taft and an affidavit of Mr. Larry Story with respect thereto that I made reference to, be submitted as a matter of record today. And I so request.

Mr. WAXMAN. Thank you, Mr. McMillan. This is the first we have heard of these affidavits. They have not been submitted to us. I think they ought to be submitted to us and put into the record, as you request.

In addition, I will ask that the October 26, 1994 article "Juiced Up" from the Wall Street Journal be printed in the record.

Let me ask further that without objection we have copies of the correspondence between the subcommittee and the U.S. Tobacco Company, including a letter of invitation to attend this morning's hearing be printed in the record as well.

And I do want to point out that we did invite Mr. Taddeo. He refused to come. He refused to send any other witness. We asked him to release one of his employees from a confidentiality agreement which would preclude him from testifying. He refused to allow this person to come and testify.

The two people that submitted affidavits would have been welcome to come and testify in person if Mr. Taddeo wished them to. I guess by an affidavit, they wouldn't be permitted—they wouldn't be in a position to have to answer any questions. But we will take these affidavits and make them part of the record.

[The information follows:]

UNITED STATES TOBACCO COMPANY
100 WEST PUTNAM AVE., GREENWICH, CONNECTICUT 06830

April 22, 1994

JOSEPH R. TADDEO
President

(203) 622-3643

The Honorable Henry A. Waxman
Chairman, Subcommittee on Health and the Environment
Committee on Energy and Commerce
United States House of Representatives
2415 Rayburn House Office Building
Washington, D.C. 20515-6115

Dear Congressman Waxman:

I am writing on behalf of United States Tobacco Company ("Company") in response to various requests which were made of the Company during the hearing on April 14, 1994 before your Subcommittee:

(1) With respect to Rep. Synar's request for all tests, reports and notes regarding in-house animal laboratory testing, the Company does not have any such documents;

(2) With respect to Rep. Synar's request regarding smokeless tobacco and health research funded through the Smokeless Tobacco Research Council (STRC), enclosed are the STRC Annual Reports from 1982 to 1993;

(3) With respect to your request for all in-house "human studies to measure nicotine levels in blood and studies related to nicotine addiction", the Company does not have any such documents;

(4) With respect to Rep. Synar's request regarding studies done on the effectiveness of the Joe Camel advertising campaign, the Company does not have any such documents;

(5) With respect to your request as to the use of tobacco extract and the nicotine content thereof, the Company does not add tobacco extract as an ingredient in the manufacture of its smokeless tobacco products.

A number of the Subcommittee's other inquiries or requests relate to the cigarette manufacturing process. We have not addressed those matters because the Company does not manufacture cigarettes.

In addition, with respect to Rep. Wyden's question as to whether the smokeless tobacco industry is going to make public the industry ingredient list submitted to the Department of Health and Human Services (HHS) pursuant to the Comprehensive Smokeless Tobacco Health Education Act, the Company is in the process of consulting with other members of the industry to address his request.

I trust that this letter responds fully to the Subcommittee's various requests as they relate to the Company.

Sincerely,

Joseph R. Taddeo

Joseph R. Taddeo

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

2415 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6118
PHONE (202) 225-4992

May 19, 1994

Mr. Joseph R. Taddeo
United States Tobacco Company
100 West Putnam Ave.,
Greenwich, Connecticut 06830

Dear Mr. Taddeo:

I appreciate receiving your April 22 response to the Subcommittee's request for additional information concerning oral tobacco manufacturing processes and related research and marketing practices by your company. Your submission of the Smokeless Tobacco Research Council's Annual Reports from 1982-1993 is helpful but it will be necessary to request additional information to clarify and complete the hearing record of April 14.

This letter clarifies the Subcommittee's document request and includes requests for additional documents and information that the Subcommittee seeks. In general, for each research study identified, include the names of individuals involved in conducting the research, the geographic location where the research was conducted, and the names of company managers who were aware of the research or its results. If such individuals are no longer employed by your company, provide all information in your possession regarding their current address and phone number.

1. State whether your company supports directly or indirectly any human or animal research through entities other than the Smokeless Tobacco Research Council. In answering this question include specific and detailed information concerning both behavioral as well as biomedical research.

2. Can you assure the Subcommittee that the research projects referenced in the STRC Annual Reports represent a full disclosure of all research supported by the STRC directly or through third parties? If not, provide a detailed description of all research supported by STRC funding for the period 1982-1993. Such description should include a detailed abstract identifying the name of the investigator, the location where the research was performed, the purpose of the research, conclusions, funding provided to carry out the work, and whether any of the research was ever incorporated, directly or indirectly, into any marketed product or marketing campaign.

3. In your letter of April 22, you indicate USTC does not have documents regarding "tests, reports and notes regarding in-house animal laboratory testing." Between 1960 - 1994 has USTC supported in-house or through third parties animal laboratory testing? If documents concerning such work do not exist, provide a written description of such

laboratory testing including the location, purpose and outcome of each such research project, and the amount of funding provided to carry out the work.

4. In your letter of April 22 you indicate USTC does not have documents regarding "in-house 'human studies to measure nicotine levels in blood and studies related to nicotine addiction'." Between 1960 - 1994 has USTC supported in-house or through third parties (other than SCRC) research or testing involving the measurement of nicotine levels in blood? If documents concerning such work do not exist, provide a written description of such laboratory testing including the location, purpose and outcome of such research, and the amount of funding provided to carry out the work.

5. Between 1980-1994 has USTC conducted or supported through an organization other than STRC research into the development of nicotine analogs? If so, provide the Subcommittee a detailed description of this research including the specific chemical studied, the location and outcome of each research project.

6. Has USTC conducted or supported behavioral or market research relating to the tobacco preferences of individuals between the ages of 18 and 34? Provide the Subcommittee with a copy of all such research for the period 1970-1994.

7. Provide for the Subcommittee a description of the specific manufacturing steps in which the nicotine or alkaloid level for each of your company's oral tobacco products are measured. In addition, provide a description of the relative nicotine levels by weight and as a percentage for each brand of oral tobacco manufactured by USTC during the period 1980 - 1994. With respect to such differences, provide the Subcommittee with a detailed description of how such differences are achieved?

8. Provide the Subcommittee with copies of all documents in the possession or under the control of your company relating to nicotine's addictiveness or lack of addictiveness, including all reports, memoranda, or other documents relating to research on nicotine's addictiveness.

9. Does USTC utilize reconstituted tobacco in the manufacture of any of its oral tobacco products? If so, what is the nicotine concentration of reconstituted tobacco for each brand of oral tobacco manufactured by USTC for the period 1982 - 1994? Provide a description of how the nicotine concentration is achieved.

Your April 14 testimony states: "U.S. tobacco does not . . . . control the nicotine content of its tobacco products before, during or after the manufacturing process." In order to better understand this statement, respond to the following questions.

10 a. In the manufacturing of smokeless tobacco does the nicotine level decline from the level present in the unprocessed leaf? If so, identify all points during the manufacturing process in which your company restores any nicotine lost during earlier steps in the manufacturing process. Also provide a detailed explanation for how nicotine levels in the unprocessed tobacco leaf used by your company are determined both before and after purchase.

10 b. Describe each manufacturing process that adjusts, however incrementally, the nicotine level of your product.

11. Although you acknowledge in your testimony the finding of the Surgeon General

that smokeless tobacco was a cause of mouth cancer, you stated in response to a question from Mr. Synar that "Oral tobacco has not been established as a cause of oral cancer." Describe the nature of scientific evidence sufficient for your company to acknowledge that oral tobacco had been established as a cause of oral cancer?

12. USTC purchases denatured alcohol for the purpose of serving as "a carrying agent for the application of certain flavorings that do not dissolve in water." Identify the name and address of the company from whom denatured alcohol was purchased during the last five years.

13. You have testified that "The assertion that smokeless tobacco use can be addictive is without merit." Provide for the Record an explanation of the scientific basis for determining the addiction liability of a substance in humans. In answering this question, cite specific medical or scientific authorities upon which your explanation is based. With respect to nicotine, provide the Subcommittee with the specific criteria necessary for your company to acknowledge the addiction liability of nicotine containing oral tobacco.

14. You have testified that USTC does not want children or those under the age of 18 to use oral tobacco products. Does your company support the enforcement of laws prohibiting the sale of oral tobacco products to minors? If so, provide for the Subcommittee a description for (1) how enforcement of such laws should be promoted, (2) how retailer compliance can most effectively be monitored and (3) what, if any, penalty should be levied upon retailers selling oral tobacco products? With respect to each case, cite evidence that the proposed strategy recommended would produce verifiable and replicable effects in reducing illicit sales to youth.

15. Provide the Subcommittee with a State-by-State breakdown of annual expenditures by your company from 1982 - 1994 which were allocated to ensure adherence to minimum age of sale laws.

16. P.L. 102-321 required States to enact and enforce minimum age of sale laws for tobacco products. Provide information on the amount and purpose of expenditures by your company, directly or indirectly, regarding state regulation of tobacco sales for representation before state legislatures for each year between 1989 - 1994.

17. Provide for the Subcommittee an estimate by year of the total sales for each of your oral tobacco products resulting from underaged purchases? Provide this information for the period 1989 - 1994

18. Provide for each year since 1980, advertising and promotional expenditures for the following brands of oral snuff

Happy Days
Skoal Bandits
Skoal Long-cut
Skoal
Copenhagen

In providing this information use the Federal Trade Commission's categories of advertising and promotional expenditures.

19. Provide for the Subcommittee information on the relative ages of oral tobacco users for each of USTC oral tobacco products for each of the years 1982 -1994.

20. Green tobacco sickness is said to be a form of nicotine poisoning which occurs when field workers touch wet tobacco. Enclosed is a copy of articles from the Journal of the American Medical Association and the Centers for Disease Control's Morbidity and Mortality Weekly Report which describe the illness. Describe what, if any, steps your company has taken during the period 1982 - 1994 to reduce the risks of this disease among tobacco field workers. During this same period has your company financed research into preventing or improving available treatment for this illness? If so, describe the nature of such research and the relevant outcomes.

21. In the past representatives of your company have expressed the position that advertising in the U.S. is not directed at individuals under the age of 18. Is this also your company's policy in advertising and promoting oral tobacco sales in Asia, South America and Eastern Europe?

22. Provide the Subcommittee with a definition for the term "tobacco satisfaction."

23. You state in your testimony that USTC does not employ a graduation strategy in the marketing of oral tobacco products and have characterized the strategy as a "fanciful concept . . . . created by plaintiff's counsel in the 1986 Marsee litigation." It is the Subcommittee's understanding that a number of documents concerning nicotine and the so-called "graduation strategy" were offered but not admitted as evidence. Submit to the Subcommittee all documents offered to the Court in the Marcee litigation but not admitted into evidence dealing with the issue of nicotine and or the graduation strategy.

Due Date

The record for the April 14 hearing is being kept open until June 3, 1994. Please respond in full to the document requests and questions in this letter by this date. If you have any questions about this inquiry, or if you anticipate any problems in responding fully by June 3, 1994, please contact Ripley Forbes of the Subcommittee staff at (202) 226-7620.

With every good wish, I am

Sincerely,

Henry A. Waxman

HENRY A. WAXMAN
Chairman, Subcommittee on
Health and the Environment

HAW/jkm
enclosures

Original Contributions

Green-Tobacco Sickness

An Illness of Tobacco Harvesters

Stephen H. Gehlbach, MD; Wilton A. Williams; Larry D. Perry; Jimmie S. Woodall

• Tobacco-associated occupational illness occurs regularly in North Carolina tobacco fields. Green-tobacco sickness is a self-limited illness characterized by pallor, vomiting, and prostration. It occurs principally in young men who handle uncured tobacco leaves in the fields. A survey among 53 harvesters who had had green-tobacco sickness and 49 control harvesters was undertaken to define and quantify the symptom complex. The illness was correlated with cropping (picking) the tobacco while it was wet; the absorption of nicotine from the tobacco leaf is the probable cause. Cigarette smoking affords protection against the illness.

(*JAMA* 229:1880-1883, 1974)

EACH year many workers who harvest North Carolina's $500 million tobacco crop develop a tobacco-associated occupational disease. The illness, although known for many years to farmers and workers, is virtually undescribed in the medical literature. Green-tobacco sickness, as it is known colloquially, is a self-limited illness that occurs in workers who handle uncured tobacco leaves. It is characterized by headache, pallor, nausea, vomiting, and prostration. Its prevalence and etiology are unknown. Because symptoms mimic organophosphate insecticide poisoning and heat exhaustion, the disease may be treated inappropriately.

Only one communication about tobacco sickness appears in the literature. In 1970, Weizenecker and Deal[1] reported their preliminary observations on 68 workers with complaints of tobacco sickness, who were seen in a rural health clinic. Symptoms of weakness, nausea, and vomiting would occur in tobacco croppers (those who pick the leaves) one hour after they began work and would last for about six hours. Weizenecker and Deal hypothesized that an unknown emetic substance contained in the tobacco sap was absorbed through the harvesters' skins. Nicotine was not considered the responsible agent.

The occurrence of illness in North Carolina tobacco fields has been recognized by physicians and health workers for many years. Illness has been attributed principally to dermal absorption of the pesticide residues on the tobacco leaves, although heat exhaustion, malingering, and a variety of other causes have also been suggested.

When harvesting begins in late June, workers walk between rows, pull green tobacco leaves from the stalks, and carry the leaves under their arms to wagons that follow them in the rows. The croppers are covered with a sticky gum from the leaves and are often drenched with dew while working. The leaves are hauled to a barn where another group strings them on poles to be hung in the barn for curing. Stringers are usually women who wear protective plastic aprons. After curing, leaves are taken from the poles and packed in burlap sheets in preparation for marketing. Although the tobacco is handled during many stages of crop production, illness occurs almost exclusively among workers who handle the green leaves in the field.

REPORT OF A CASE

A 12-year-old boy was admitted to the hospital because of vomiting and weakness. His parents registered the complaint of tobacco poisoning. At 7 AM on the day of admission, the boy had begun cropping tobacco for a neighbor. By midafternoon, he complained of a headache and slight dizziness, and on returning home, had abdominal cramps, nausea, and vomiting. His mother reported that he was extremely pale and "too weak to get up from the floor." The vomiting persisted, and he was brought to the emergency room at 10:30 PM.

History was remarkable only for previous episodes of vomiting and prostration after harvesting in tobacco fields. He became ill every time he cropped (approximately six to ten times each season). He had had two hospital admissions during the past two years when these episodes of tobacco sickness were particularly severe.

From the pesticides program, Division of Health Services, North Carolina Department of Human Resources, Raleigh.

Reprint requests to Division of Health Services, P.O. Box 2091, Raleigh, NC 27602 (Dr. Gehlbach).

Recovery had occurred within 24 hours on both occasions. The patient does not smoke. His father was also susceptible to tobacco sickness as a young man, but stopped getting sick when he began smoking regularly.

At physical examination, the patient appeared pale and exhausted. His oral temperature was 36 C (96.8 F); pulse, 96 beats per minute; respirations, 22/min; blood pressure, 114/80 mm Hg. The results of the rest of his examination were unremarkable; his lung fields were clear, abdomen nontender, and results of neurologic examination normal. Results of a complete blood cell count, urinalysis, and serum electrolyte determinations obtained the next morning were within normal limits.

The patient was treated with intravenously administered fluids and antiemetics and his condition was greatly improved by morning.

Table 1.—Harvesting Occupations of 53 Workers With Tobacco Sickness and 49 Control Subjects

	Cases of Tobacco Sickness		Control Subjects	
	No.	%	No.	%
Field cropper	48	91	30	61
Stringer at barn	5	9	15	31
Tractor driver	0	0	4	8
Total	53	100	49	100

Table 2.—Distribution by Age, Race, and Sex

	Workers With Tobacco Sickness (n=53)		Control Subjects (n=49)	
	No.	%	No.	%
Age				
Median	15	...	16	.
Mean	18.7	.	20.1	.
Standard deviation	10.8	...	11.8	.
Sex				
Male	43	81	27	55
Female	10	19	22	45
Race				
White	44	83	41	84
Black	3	6	5	10
Indian	6	11	3	6

Table 3.—Onset of Tobacco Sickness in 53 Workers

Time	No.	%
Before noon while working	7	13
Afternoon while working	17	32
Afternoon or evening after work	27	52
Next day	1	2
Total	52	100

Table 4.—Symptoms of Tobacco Sickness (n=53)

	No.	%
Nausea, vomiting	52	98
Pallor	47	89
Weakness	43	81
Dizziness, light-headedness	43	81
Headache	43	81
Increased sweating	29	55
Abdominal pain	22	42
Cold, chills	19	36
Increased salivation	9	17

Table 5.—Duration of Illness (n=53)

	No.	%
<12 hr	17	32
12-24 hr	30	57
24-48 hr	5	9
>48 hr	1	2
Total	53	100

Table 6.—Smoking History

	Male Croppers With Tobacco Sickness (n=46)*		Male Cropper Control Subjects (n=24)*	
	No.	%	No.	%
Nonsmoker	37	93	10	42
Smoker	3	7	14	58

*$\chi^2 = 17.35$, $P < .001$.

METHODS

During August and September 1973, several rural health clinics and physicians' offices were contacted in an attempt to identify patients who complained of tobacco sickness or had had symptoms and exposure history compatible with the disease. In addition, 196 farmers from nine tobacco markets across the tobacco belt (eastern North Carolina) were interviewed and asked to identify any of their workers who had become ill while harvesting tobacco during the recent season. The criteria for classifying illness as green-tobacco sickness were (1) characteristic symptoms, (2) recurrence of the illness on repeated harvesting exposures, (3) self-limited nature of the illness, and (4) pesticide exposure insufficient to cause illness. Fifty-three cases that met these criteria were located and the patients were interviewed by the authors. The same questionnaire was administered to a group of control subjects selected from either family members of ill persons who worked in tobacco, but did not get sick, or from people who worked in fields where illness occurred, but did not become ill themselves. Forty-nine control subjects were selected.

RESULTS

Tobacco sickness occurred in croppers (Table 1); young, white men were principally affected. Their median age was 15 years; only ten were girls. Cropping was the job most frequently associated with illness (Table 2). Blacks were underrepresented; although they comprised an estimated 58% of the work force, they represented only 6% of our cases.

The episodes of illness tended to occur in clusters. The 53 cases occurred on only 28 farms. More than one member of a family was frequently affected, with 22 of the cases occurring in eight families. Most affected individuals reported a history of tobacco sickness in previous years. Of the 53, 62% had been sick in other years, and 9% were working in tobacco for the first time. Four control subjects had been sick in past years (they had subsequently decreased their exposure to tobacco leaf, and two had begun smoking). It was difficult to quantitate the exact number of times individuals were ill, but almost all of the patients were sick on two or more occasions; several reported more than ten episodes.

All cases reported getting soaked with dew while working, and most noted an increased likelihood of becoming ill when the tobacco was especially wet, ie, during or after a rain. Some said that harvesters who were susceptible to the illness would not get sick if they stayed out of the field until later in the day when the tobacco had dried. Most patients also noticed a particularly strong odor to the green tobacco. Many said it alone could make them nauseated and light-headed.

Symptoms

The symptom complex described was remarkably consistent. Onset was usually in the afternoon, either in the field or after returning home (87% of cases), although exposure began in the early morning (Table 3). Headache and nausea led to severe vomiting, pallor, and prostration. Table 4 lists symptoms by frequency of occurrence. Several people likened the experience to extreme seasickness. Duration was generally short; 89% of those having illness had recovered in 24 hours (Table 5).

Control subjects were also questioned about symptoms. Only three reports of headaches and one report of dizziness were elicited.

Smoking

The most striking finding of the survey was that cigarette smokers rarely get tobacco sickness. A number of farmers who were interviewed reported that they had personally experienced tobacco sickness until they began smoking regularly. A few noted a return of their susceptibility when they stopped smoking. Only two (4%) of the cases surveyed were in regular smokers, compared with 18 (37%) in the controls. Three other patients and two controls admitted to occasional smoking (one or two cigarettes per day). The rest were nonsmokers (91% of cases, 59% of controls). No one used other forms of tobacco. In comparing male croppers' (the group accounting for most illness) cases and control subjects for smoking history, with the use of the chi-square statistic with Yates' correction factor, we can see a striking protective effect of smoking (Table 6) ($P<.001$).

Etiology

The discovery that tobacco sickness occurred in fields where organophosphate and carbamate insecticides had not been sprayed is perhaps the most compelling argument against pesticides as a causative agent. Fifteen cases of tobacco sickness occurred on eight farms that did not use these compounds. The recurrent, self-limited nature of green-tobacco sickness further sets it apart from pesticide poisoning. Because inhibition by organophosphate compounds is largely irreversible, and cholinesterase levels remain depressed for weeks after clinical recovery, it is unlikely that individuals could become ill on repeated entry into tobacco fields and recover without vigorous therapy if pesticides were responsible. A number of our patients cropped twice weekly and reported sickness every time they cropped.

Heat exhaustion is also an unlikely cause of tobacco sickness. Although tobacco harvesting is usually done in hot weather, episodes occurred on rainy days when workers reported feeling cold rather than overheated. More than half of the patients became sick after they had gone home.

COMMENT

Evidence suggests that green-tobacco sickness is caused by a toxic product elaborated by wet, raw tobacco leaves. Because nicotine is pharmacologically the most potent constituent of tobacco, it seems to be the likely agent. A tobacco leaf contains 1.5% to 4% nicotine by dry weight.[7]

Human poisonings from nicotine insecticides and from accidental overdoses of tobacco are well described. Symptoms include parasympathetic and sympathetic manifestations.[3] Weakness, pallor, headache, dizziness, nausea, sweating, prostration, and vomiting, which were observed in cases of green-tobacco sickness, are commonly noted.[4-6] Symptoms associated with severe nicotine poisoning, such as diarrhea, convulsions, dyspnea, and vascular collapse, were not seen in our patients, however. Symptoms that are ascribed to nicotine intoxication in novice smokers mimic green-tobacco sickness.

Nicotine is absorbed by a variety of routes including the lungs, gastrointestinal tract, and intact skin. Faulkner[6] and Wilson[7] each discuss cases of poisoning from dermal contact with nicotine insecticides. McNally[6] and Wilson[7] mention the occurrence of poisoning after topical application of tobacco leaf poultices to the skin. Occurrence of illness after nonsmoking respiratory exposure is suggested by Samitz et al[8] who note that one of every 1,000 workers in a cigar factory he studied was sensitive to the smell of tobacco. Nausea and vomiting developed in workers each time they entered the plant.

The association made between illness and contact with the wet tobacco and its odor suggests a combined dermal-respiratory exposure in tobacco sickness. The greatest exposure would be among croppers in the field. Moisture on the tobacco leaves probably acts as a solvent for the nicotine, facilitating dermal absorption when clothes become wet and cling to the workers' bodies.

The survey confirmed a strong association between occurrence of illness and nonsmoking. The explanation for the protective role of smoking may be that tobacco workers who smoke are tolerant to the amount of nicotine absorbed during harvesting. Johnston[10] found that smokers could withstand four times the paren-

teral dosage of nicotine that caused symptoms in nonsmokers. Those few smokers who do become ill probably absorb nicotine in excess of their acquired level of resistance.

Several observations made during the study raise important questions that need further exploration. The low frequency of sickness in black workers was not expected. Well over 50% of the harvesting work force is black, but only three of the 53 patients were black. This difference is probably related to inequities in the reporting of illness. Because most tobacco sickness occurs after working hours, and most of the growers interviewed were whites who have little interaction with blacks after work, farmers may have been unaware of illnesses that occurred.

The relatively long latency period between the beginning of work (usually 7 AM) and the onset of symptoms in the late afternoon is also puzzling. In most cases of nicotine poisoning described in the literature, symptoms begin within an hour of exposure. Because the tobacco is wettest from dew in the early morning, the first few hours of work should represent the period of greatest absorption. Projected field studies may provide answers to these questions.

Philip F. White, MD, and Thomas K. Ross, MD, gave permission to report the case.

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The Art of Medicine—Part V: In concluding this series of "tips and tricks" [Part I, Aug 26, p 1199; Part II, Sept 2, p 1348; Part III, Sept 9, p 1440; Part IV, Sept 23, p 1800], I would like to give you a few quick ones. To be sure whether a lump has grown, measure it—of course. Do this by outlining it horizontally and vertically with a pen dot and then measuring it. But write it down on the patient's record. Otherwise, you'll never be able to guess how big it was two weeks and 200 patient-visits ago. Also, did you know that the patient can feel the difference within his chest when you percuss the two sides, if there is pathology in one. It's true—try it. Also, the sounds of auscultation are different when listening to a chest if the patient has one arm higher such as resting it on the desk. Insist that he put both arms down to his side; it makes it more accurate. "Stick your tongue out and say ah" may work sometimes but if it doesn't, try telling the patient not to put the tongue out or in but let it go where it wants to. "Just pretend you don't have a tongue" I tell them, and it will usually stay in the bottom of the mouth where it belongs, giving you a better view so you will see more.

When examining small children, always stay in front of them. I guess they are suspicious unless they can see you all the time. Especially when examining the chest, anything that keeps the "little monsters" from crying or wiggling makes auscultation a welcome haven. And save the "squirming" areas of the examination for last. In that way, you will not have to go through most of it under duress. I remember a child some years ago who was a perfect little angel throughout the entire examination, shot and all, until I went to weigh him, of all things. He fought and screamed so much, I never did find out his weight.

So, these are just a few of the little "gimmicks" I have learned over the years. I'm sure all of you have some that slipped my mind or I never learned. It would be nice to hear about them. But the best gimmick of all, the one that keeps a doctor's enthusiasm for his practice as the years go by is based on one thing—whatever it is that causes his patients to treat him with the respect and consideration that somehow is not reserved for other professionals—the nice things they do and say, little thank you notes they write, and love they convey that doesn't make their medical record but does crawl into your heart. I just hope this changing world doesn't disturb that.—I. L. Marks, MD, Silver Spring, Md

April 9, 1993 / Vol. 42 / No. 13

MMWR
MORBIDITY AND MORTALITY WEEKLY REPORT

237 Green Tobacco Sickness in Tobacco Harvesters — Kentucky, 1992
240 Emergency Mosquito Control Associated with Hurricane Andrew — Fla. and La.
242 Injuries and Illnesses Related to Hurricane Andrew — Louisiana, 1992
251 Years of Potential Life Lost Before Age 65
254 Adult Blood Lead Epidemiology and Surveillance — United States
256 Notice to Readers

Epidemiologic Notes and Reports

Green Tobacco Sickness in Tobacco Harvesters — Kentucky, 1992

Green tobacco sickness (GTS) is an illness resulting from dermal exposure to dissolved nicotine from wet tobacco leaves; it is characterized by nausea, vomiting, weakness, and dizziness and sometimes fluctuations in blood pressure or heart rate (*1–3*). On September 14, 1992, the Occupational Health Nurses in Agricultural Communities (OHNAC) project of Kentucky* received reports of 27 cases of GTS. The cases occurred among tobacco harvesters who had sought treatment in several hospital emergency departments in south-central Kentucky during the preceding 2 weeks. This report summarizes the findings of the investigation of these cases.

On September 15, OHNAC staff initiated a review of inpatient and emergency department medical records from May 1 through October 2 at five hospitals in the Bowling Green and Elizabethtown areas. The review identified 55 persons in whom GTS, nicotine poisoning, or other illnesses compatible with GTS symptomatology had been diagnosed. On September 25, industrial hygienists from CDC's National Institute for Occupational Safety and Health (NIOSH) observed the tobacco-harvesting process. Worker's hands, forearms, thighs, and backs received the most dermal exposure to wet tobacco. Dew from tobacco leaves often saturated workers' clothing within minutes of beginning field work.

To evaluate possible risk factors associated with GTS, NIOSH investigators and occupational health nurses from the OHNAC project conducted a case-control study. A case was defined as an emergency department diagnosis of GTS or nicotine poisoning in a person whose recorded work history included tobacco harvesting at the time of illness. Forty-nine persons met the case definition, with episodes occurring from July 25 through September 19, 1992; two cases were subsequently excluded from analysis because illness onset coincided with exposure to pesticides (which can induce similar symptoms). Median age of the 47 case-patients was 29 years (range:

*OHNAC is a national surveillance program conducted by CDC's National Institute for Occupational Safety and Health (NIOSH) that has placed public health nurses in rural communities and hospitals in 10 states (California, Georgia, Iowa, Kentucky, Maine, Minnesota, New York, North Carolina, North Dakota, and Ohio) to conduct surveillance of agriculture-related illnesses and injuries that occur among farmers and their family members. These surveillance data are used to reduce the risk for occupational illness and injury in agricultural populations.

Green Tobacco Sickness — Continued

14–54 years); 41 (87%) were male. Controls were 83 asymptomatic tobacco harvesters referred by case-patients or local agricultural extension agents. Their median age was 39 years (range: 16–70 years); 72 (87%) were male.

Twelve (26%) case-patients were hospitalized for 1–2 days; of these, two (4%) required intensive-care treatment for hypotension and bradycardia. All case-patients were initially treated in emergency departments with antiemetic drugs, and 35 (74%) received intravenous fluids.

Forty of 47 case-patients and 83 controls were administered a questionnaire by telephone. Respondents were asked about the types of jobs performed during the tobacco growing season, use of protective clothing, exposure to wet tobacco leaves, work in wet clothing, work duration, and personal tobacco use.

Among the 40 case-patients who completed interviews, the median time from starting work to onset of illness was 10 hours (range: 3–17 hours); most frequently reported symptoms included weakness (100%), nausea (98%), vomiting (91%), dizziness (91%), abdominal cramps (70%), headache (60%), and difficulty breathing (60%). The mean duration of illness was 2.4 days. Thirty-six (90%) had previous work experience with tobacco. Of these, 14 (39%) had previously sought medical care for symptoms suggestive of GTS. Seventeen (85%) of 20 case-patients aged ≥30 years attributed their illness to working in wet tobacco, compared with 12 (60%) case-patients aged <30 years.

Age <30 years was a risk factor for illness (odds ratio [OR]=3.1; 95% confidence interval [CI]=1.4–7.0). All case-patients and 69 (83%) controls had worked in fields of wet tobacco where their clothes became wet (OR=infinite; lower confidence limit=1.8). Current use of personal tobacco products (i.e., cigarettes, snuff, chewing tobacco, pipe, or cigars) appeared to be weakly protective, but the estimate was not statistically significant (OR=0.7; 95% CI=0.3–1.5). Sex and work duration (i.e., number of hours per day or number of days per week) were not associated with illness. The reported use of protective clothing was similar for case-patients and controls; for case-patients and controls combined, reported use of protective items worn at least once during the growing season was 5% for waterproof clothing and 32% for gloves.

Representative hospital costs were calculated for three levels of care received by 31 case-patients treated at two participating hospitals. Fees averaged $250 for outpatient treatment, $566 for hospital admission, and $2041 for intensive-care treatment.

Reported By: B Boylan, MS, Lincoln Trail District Health Dept, Elizabethtown; V Brandt, Barren River District Health Dept, Bowling Green; J Muehlbauer, Buffalo Trace District Health Dept, Maysville; M Auslander, DVM, C Spurlock, PhD, Injury Epidemiology Section; R Finger, MD, State Epidemiologist, Kentucky Dept for Health Svcs. Hazard Evaluations and Technical Assistance Br, and Surveillance Br, Div of Surveillance, Hazard Evaluations, and Field Studies, National Institute for Occupational Safety and Health, CDC.

Editorial Note: Before 1992, no cases of GTS had been reported to Kentucky public health agencies. Increased surveillance of adverse health events in persons working in agriculture and increased awareness of the condition may explain the reports in Kentucky during this harvest season (i.e., late summer). Before the NIOSH investigation was initiated, OHNAC occupational health nurses had supplied emergency department physicians with literature about GTS. In addition, rainfall during the 1992 season was uncharacteristically heavy, potentially increasing exposure to wet tobacco and incidance of GTS.

Green Tobacco Sickness — Continued

The lower risk for GTS among older workers may result from work practices developed over time that reduce contact with wet tobacco. In addition, workers likely to develop symptoms of GTS may leave this work force at a young age. One potential limitation to these findings is that the age distribution of controls may not reflect the local population of tobacco workers.

Personal use of tobacco products may be weakly protective, probably because of development of tolerance to the effects of nicotine among regular tobacco users. Tolerance may not be protective if dermal absorption substantially exceeds the user's customary nicotine intake (*4*), which may have occurred in this outbreak because of heavier than usual rains.

Approximately 60,000 persons harvest tobacco annually in Kentucky at least part-time (*5*). The estimated crude 2-month incidence rate of hospital-treated GTS among tobacco workers in the five-county study area was 10 per 1000 workers.† Statewide extrapolation of this incidence rate suggests as many as 600 persons in Kentucky could have sought emergency department care for the condition. However, this figure may underestimate the true incidence of GTS because many affected persons may not seek hospital treatment (*2*).

Use of protective clothing (e.g., water-resistant clothing and rubber gloves) reduces the amount of nicotine absorbed by workers in contact with green tobacco (*6,7*). Tobacco farm owners should inform their employees of the hazards associated with harvesting wet tobacco and the importance of safe work practices in preventing GTS; discuss routes of exposure and symptoms associated with the disease; advise workers to change into clean, dry clothing and boots during the work day if these become wet; and allow flexible work hours to avoid work during or immediately after a rainfall. Health-care providers in areas where tobacco is harvested should consider GTS in workers who present with symptoms similar to those reported here.

To determine whether GTS regularly occurs or whether this outbreak was due to an unusually wet growing season, the OHNAC project of Kentucky will continue active surveillance for GTS in local hospitals and clinics during tobacco growing seasons. The Kentucky Department for Health Services will disseminate information on GTS to health-care professionals and institutions statewide. Workers will be informed about the condition and preventive measures through the Cooperative Extension Service and through press releases to community newspapers.

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U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

2415 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6118
PHONE (202) 225-4952

October 31, 1994

Mr. Joseph R. Taddeo
United States Tobacco Company
100 West Putnam Ave.
Greenwich, Connecticut 06830

Dear Mr. Taddeo:

I am writing to request your cooperation in providing the Subcommittee with information on the pH of smokeless tobacco products manufactured by your company during the period 1987-1994. This information should be displayed and arranged in the same format as your July 22nd submission on the percent of nicotine by weight (UST Doc # 07001-07002).

In addition, I would appreciate your written response to the following questions pertinent to the relationship between the bioavailability of nicotine and tobacco product alkalinity.

1) Do any processes used by your company in the curing of tobacco or in the manufacture of any smokeless tobacco products increase the pH? If so, what is the purpose of such increase and how is the increase achieved? Identify any ingredients used and added to tobacco or tobacco packaging in the manufacturing process which would have the effect of increasing the alkalinity of the smokeless tobacco product.

2) Are sodium carbonate and/or ammonium carbonate added to your smokeless tobacco products during the manufacturing process? If so, describe the purposes for the use of such additives.

3) How does the length of time a product is stored following packaging affect the alkalinity of your smokeless tobacco products?

4) Does the pH of a smokeless tobacco product affect the relative bioavailability of nicotine for users? If so, how? On average, does the consumer of a smokeless product with low pH absorb a lower level of total nicotine than a consumer of a smokeless product with a high pH? For the purpose of responding to this question, assume that each smokeless tobacco product contains approximately the same percent of nicotine by weight.

Please forward the requested information to the Subcommittee offices in Room 512 O'Neill House Office Building, Washington, D.C. 20515 no later than Friday, November 18, 1994. If you have any questions concerning this request, please contact Ripley Forbes of the Subcommittee staff at 202-226-7620.

Your continuing cooperation is greatly appreciated.

With every good wish, I am

Sincerely,

Henry A. Waxman

HENRY A. WAXMAN
Chairman, Subcommittee on
Health and the Environment

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
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PHONE (202) 225-4952

November 18, 1994

Mr. Joseph Taddeo
President
U.S. Tobacco Company
100 West Putnam Avenue
Greenwich, CT 06803

Dear Mr. Taddeo:

I am writing to invite you to testify at an oversight hearing on smokeless tobacco, including the bioavailability of nicotine in tobacco products manufacturered by your company, its relationship to nicotine addiction and the use of such products by adolescents. A recent report in the Wall Street Journal has raised serious questions about the conduct of your company and your previous testimony before the Subcommittee to which I would like to give you the opportunity to respond. The hearing will be held at 11:00 a.m. on Tuesday, November 29, 1994, in the Rayburn House Office Building. A room for the hearing will be announced shortly.

I am again requesting your cooperation in providing the Subcommittee with the documents and requests for information made in my letters of May 19, 1994, and October 31, 1994. I remind you that you agreed at our hearing on April 14, 1994, to cooperate fully with the Subcommittee's tobacco product manufacturing inquiry. These materials should be forwarded to the Subcommittee's offices in Room 512 of the O'Neill House Office Building no later than Friday, November 25, 1994.

I also request that you waive the confidentiality agreement between Ken Carlsen, a former division manager, and U.S. Tobacco. Mr. Carlsen, who is identified as having relevant information in the Wall Street Journal article, has informed the Subcommittee that he is unable to discuss his work at U.S. Tobacco with the Subcommittee or at a hearing until he is released from the confidentiality agreement.

I ask that you respond in writing to the request to waive Mr. Carlsen's confidentiality agreement by the close of business on November 22, 1994. In addition, you should submit 200 copies of written testimony no later than noon on Monday, November 28, 1994. Please deliver the testimony to 512 O'Neill House Office Building, 300 South New Jersey, SE, Washington, D.C. 20515. The written testimony may be of any length. However, I must ask that you limit your oral statement to 10 minutes.

If you have any further questions, please contact Ripley Forbes or Phil Barnett of my Subcommittee staff at (202) 226-7620.

With every good wish, I am

Sincerely,

Henry A. Waxman

HENRY A. WAXMAN
Chairman, Subcommittee on
Health and the Environment

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November 28, 1994

HAND DELIVERED

The Honorable Henry A. Waxman
Chairman, Subcommittee on Health
and the Environment
Committee on Energy and Commerce
United States House of Representatives
2415 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Waxman:

As you have acknowledged previously, our client, United States Tobacco Company ("USTC" or the "Company"), has cooperated with the Subcommittee's tobacco inquiry. Following Company President Joseph R. Taddeo's testimony on April 14, 1994, USTC was the first to submit written responses, in a letter dated April 22, 1994, to additional questions asked by the members during the hearing. The Company was first, on July 22, 1994, to provide written responses to your letter dated May 19, 1994. At that time, the Company submitted a 45-page memorandum and provided hundreds of documents in response to questions 1-13 of that correspondence.

USTC wishes to continue its cooperation with the Subcommittee and, in that spirit, the Company has asked us to respond to your most recent letter to Mr. Taddeo, dated November 18, 1994. First, as your staff was advised on November 16, 1994, the Company intended to complete its response to the May 19th requests during the week of November 28, 1994. The Company has completed today its answers to the remaining questions set forth in your May 19, 1994, letter. (See enclosure.) We understand that USTC will be the first tobacco company to complete its responses to your May 1994 letter requests for information and documents.

Second, with respect to the hearing scheduled for November 29, 1994, the Company is insufficiently familiar with the

intended focus of this "oversight" hearing; therefore, at this late date and without further input from the staff, the Company is unable to waive its confidentiality agreement with Ken Carlsen at this time. A blanket waiver, without limitation, would seem inappropriate. USTC would be willing to discuss this matter further with the Subcommittee.

Third, also with respect to the planned hearing, Mr. Taddeo is not available to testify on November 29, 1994, and therefore is unable to accept your invitation to appear.

Finally, the Company is reviewing your letter to Mr. Taddeo dated October 31, 1994, which asked a number of questions relating to pH values of the Company's smokeless tobacco products, over an eight-year period. In connection with that review, USTC will determine when a complete response might be made. In keeping with earlier discussions we have had with your staff, due to the breadth of the requests it was not possible for the Company to meet the requested date for the response.

With best wishes for the holiday season.

Sincerely yours,

Carl S. Rauh

Saul M. Pilchen

cc: The Honorable
Thomas J. Bliley, Jr.

AFFIDAVIT OF JAMES TAFT

I, James Taft, being duly sworn, do depose and state:

1. I worked for United States Tobacco Company ("USTC" or "the Company") from 1972 to 1991. I was a chemist in the Research & Development department, and served for a time as head of Product Development in Nashville, Tennessee.

2. Recently, I was contacted by Wall Street Journal reporter Alix Freedman. After reading Ms. Freedman's article in the October 26, 1994, issue of the Wall Street Journal, I believe she misunderstood what I told her, and drew erroneous conclusions.

3. Specifically, I did not tell Ms. Freedman, nor do I believe, that USTC ever manipulated pH levels for the purpose of increasing "free" nicotine. I disagree with the thesis of the article that USTC "doctors" its smokeless brands to "manipulate the amount of nicotine that users absorb."

4. My experience at USTC was that products were developed according to taste preferences of consumers. Achievement of certain "free" nicotine levels was never discussed as part of the product development process.

5. In sum, I am sure that what I told Ms. Freedman did not constitute any support for allegations that USTC has "spiked products to boost nicotine delivery."

James Taft

11-8-94
Date

SUBSCRIBED AND SWORN TO before me, a Notary Public in and for the County of Davidson, Tennessee this 8th day of November, 1994.

Barbara J Hatton

My Commission Expires:

March 23, 1996

AFFIDAVIT OF LARRY STORY

I, Larry Story, being duly sworn, do depose and say:

1. I was employed by United States Tobacco Company ("USTC" or "the Company") from 1967 to 1982, as a chemist in the Research & Development department located in Nashville, Tennessee.

2. In recent months, I was contacted by telephone on several occasions by Alix Freedman, a reporter from the Wall Street Journal, and asked questions about the Company's manufacture of moist snuff products. I have reviewed the article written subsequently by Ms. Freedman, dated October 26, 1994, and believe that comments in the article attributed to me were taken out of context and misconstrued, given what I told her during our telephone conversations.

3. In general, based on what I observed during my work at USTC, I disagree with the main premise of Ms. Freedman's article, namely, that the Company intentionally manipulated pH levels for the purpose of affecting its products' "free" nicotine. In fact, to my knowledge USTC did not "manipulate" pH levels in its products for nicotine-related reasons.

4. I understood USTC added certain ingredients to its products according to age-old formulas derived long before "free nicotine" was an issue. This process related to taste-related reasons not having to do with "free" nicotine. At no time did I inform Ms. Freedman that the Company "tinkered" with pH levels for the purpose of achieving a certain level of "free" nicotine, since this was not the case.

5. While I recall that different USTC products contained different levels of nicotine, I do not believe that, as suggested by the article, at USTC "each product occupied a specific rung on the nicotine-absorption ladder."

6. I am certain that what I told Ms. Freedman does not constitute what the article called "powerful support for allegations that the tobacco industry has spiked products to boost nicotine delivery."

Larry Story

Larry Story

November 8, 1994

Date

SUBSCRIBED AND SWORN TO before me, a Notary Public in and for the County of Davidson, Tennessee, this 8th day of November, 1994.

My Commission Expires:

March 23, 1996

THE WALL STREET JOURNAL WEDNESDAY, OCTOBER 26, 1994

Juiced Up

How a Tobacco Giant Doctors Snuff Brands To Boost Their 'Kick'

U.S. Tobacco Raises the pH, Increasing the Nicotine A User's Mouth Absorbs

Cherry Skoal for Beginners

By Alix M. Freedman
Staff Reporter of The Wall Street Journal

Travis Tippetts, an Orem, Utah, teenager, took up snuff last year after hearing his friends talk about a hot new brand, cherry Skoal Long Cut. Its sweet taste reminded him of cherry cough syrup, and Travis, then 16, liked the "little tobacco buzz." But two months later, the thrill was gone.

"Cherry wasn't satisfying me," he says. "I wasn't getting enough nicotine." So he "moved up" to Copenhagen, a brand so powerful that it can make new users gag. Cherry Skoal, he says, "is a beginner's product" that "helped me gradually go up the ladder."

The tobacco industry emphatically denies that it doctors levels of nicotine, the chemical that makes tobacco addictive, in order to make some products stronger than others. No company has been more insistent in those denials than UST Inc.'s United States Tobacco Co. unit, maker of both cherry Skoal and Copenhagen. "U.S. Tobacco does not in any way manipulate or spike the nicotine levels of its tobacco products," Joseph Taddeo, U.S. Tobacco's chief executive officer, testified before Congress in April.

The Nicotine Chain

But two former U.S. Tobacco chemists, speaking on the topic for the first time, say that while the company doesn't manipulate nicotine levels, it does manipulate the amount of nicotine that users *absorb*. U.S. Tobacco, they say, adds chemicals to boost the alkalinity of its snuff. The more alkaline the snuff is, they say, the more nicotine is released.

Their descriptions provide powerful support for allegations that the tobacco industry has spiked products to boost nicotine delivery. Two not-yet-released government studies appear to back that conclusion. U.S. Tobacco's manufacturing process also lays the groundwork for what critics allege is a "graduation" strategy: marketing lower-impact products such as cherry Skoal to first-time users, and then profiting as they move up the nicotine chain to ever more addictive brands such as Copenhagen.

U.S. Tobacco, the dominant player in the $1.1 billion snuff industry, refused to comment specifically on the manipulation of nicotine absorption. The company didn't make executives available for interviews, and asked for written questions, to which it responded in writing.

Quoting from Mr. Taddeo's congressional testimony, U.S. Tobacco said it doesn't "take any action to control the nicotine content of its tobacco products, before, during, or after the manufacturing process." In the testimony, Mr. Taddeo also denied a marketing strategy of "graduating" users from lower-nicotine to higher-nicotine products, saying that was a "fanciful concept." He added, "Like any tobacco products, our smokeless tobacco products vary in nicotine content."

A Dangerous Threat

Allegations of nicotine manipulation have emerged as a grave threat to the $22.5 billion U.S. tobacco industry. Food and Drug Administration Chief David A. Kessler has said he may use alleged nicotine manipulation as the basis to regulate tobacco as a drug. Congressional hearings last spring made much of cigarette makers' use of reconstituted tobacco—which involves removing nicotine and then adding it back later — but it was never established that this process raised nicotine levels; in fact, cigarette companies argued that the process lowers levels.

The hearings didn't focus on smokeless tobacco, an approximately $1.6 billion industry that includes both snuff and chewing tobacco. Yet U.S. Tobacco routinely adds chemicals to its snuff "to deliver the free nicotine faster and to make the product stronger," says Larry D. Story, a former company chemist who says he left voluntarily in 1982.

Snuff, which sometimes is confused with chewing tobacco, is shredded tobacco that users suck on, but don't chew. Users take a pinch, or "dip," and place it between the cheek and gum, shifting it about with their tongues and spitting occasionally. Snuff is the only segment of the tobacco industry that is growing, with U.S. volume up 3% in 1993, according to Sanford C. Bernstein & Co., an investment house.

It also is increasingly popular with children, by some measures. According to a 1992 Surgeon General report, the average age of initiation to snuff was just 9½ years. U.S. Tobacco says it markets its products only to adults. An estimated 7.5 million

people in the U.S. use smokeless tobacco, mostly snuff, compared with 53.9 million who smoke cigarettes.

'Enough to Kill a Horse'

The nicotine level of snuff — as well as that of cigarettes and cigars — is determined by how different types of tobaccos are blended. Reflecting the nicotine-rich varieties U.S. Tobacco primarily uses, James C. Taft, a chemist who was the company's head of product development from 1972 to 1991, jokes that its products "all have enough nicotine to kill a horse."

But nicotine content is only part of the equation. The other crucial variable is the amount of nicotine that is free to get quickly absorbed into a user's bloodstream. In part, this so-called free nicotine is determined by the cut of the tobacco; finely chopped particles release nicotine faster than larger pieces. More important, though, is the alkalinity of the tobacco, as indicated by the pH level. Most tobaccos used in snuff start out with a pH of less than six, which means the snuff is acid, not alkaline; nicotine isn't readily absorbed until the pH tops seven, reflecting the shift to alkalinity, scientists say.

Two former U.S. Tobacco chemists, Mr. Taft and Mr. Story, say that while they were with the company, it used certain chemicals—especially sodium carbonate and ammonium carbonate—to increase the alkalinity of its tobaccos and, thus, their levels of free nicotine. The company added these chemicals during and after fermentation, the process that turns tobacco into snuff, they say.

Ammonia, primarily a byproduct of fermentation, also "really increases the pH," Mr. Story says.)

According to Mr. Taft, "The fermentation process involves adding chemicals and, at the end, you add some more chemicals which increase pH, too." Without increasing the pH, he says, "you couldn't get nicotine release."

U.S. Tobacco declined to comment on the fermentation process or pH levels. "We cannot discuss the intricacies of our manufacturing process due to proprietary reasons," a company spokesman said in a letter. "Scores of companies from Coca-Cola to KFC have gone to extraordinary lengths to keep its formulas a closely guarded secret. . . ."

NEVERTHELESS, IN 1986, the company's then-chairman, Louis F. Bantle, testified during a liability trial that pH plays a role in nicotine absorption; he said he was "not an expert in that" and wasn't asked to elaborate. Moreover, sodium carbonate and ammonium carbonate appeared on a list of 562 additives that the snuff industry released in May to a congressional subcommittee during hearings on the tobacco industry's manufacturing and research practices. The additives were described as ingredients in edibles such as baked goods.

Snuff makers may not be alone in boosting the pH levels of their products. The FDA's Dr. Kessler has alleged that cigarette companies add ammonia to their products to boost pH levels and to free up nicotine. Cigarette makers deny the charge. In any case, government health officials believe pH manipulation isn't as crucial for cigarettes as it is for snuff, because the lung is so much more efficient in drawing out nicotine than the mouth.

U.S. Tobacco has been tinkering with the pH of its products—and with their free-nicotine levels—at least since the late 1960s, according to Mr. Story. At the time, new users were scarce and the company's results were stagnant. The chemist, who joined U.S. Tobacco in 1967, says that during his tenure, each product occupied a specific rung on the nicotine-absorption ladder. U.S. Tobacco tried to control as precisely as possible the dose that each delivered, he says. "There used to be a saying at UST that 'There's a hook in every can,'" he says. "And that hook is nicotine."

For example, Mr. Story says that in his day, the company's bestselling Copenhagen brand would emerge from fermentation with a pH of about 7.4. Then, to make it a finished product, "it was brought up to a pH of 7.8, by adding more sodium carbonate and ammonium carbonate." (Copenhagen's fermentation continues in the can, which can raise its pH considerably higher, according to Mr. Story.) Original Fine Cut Skoal, U.S. Tobacco's second-most-potent product, was formulated to wind up with a pH of 7.4, he says.

Yet both Copenhagen and Fine Cut Skoal, the company's mainstay products through the 1970s, were difficult for beginners to get the hang of. Both are made of finely chopped tobacco that tends to float messily around the mouths of new users. And both are so strong they can make new users throw up. What was needed was a starter product with a lower pH.

So by the late 1970s, Mr. Story was helping develop products that would be more accessible. First, in 1983, came Skoal Bandits, a beginner product in which the tobacco remains in a teabag-like pouch. Bandits—introduced in ads as "easy to use, anywhere, anytime"—are "a lot weaker product, nicotine-wise," Mr. Story says. Also, "you don't have to expectorate—you don't have to spit."

Then, in 1984, U.S. Tobacco introduced Skoal Long Cut flavors, made from bigger pieces of tobacco that "pack" more easily, somewhat like chewing gum. The bigger pieces also don't release nicotine as fast as the tiny particles of Copenhagen and Fine Cut, Mr. Story says. The idea of Skoal Long Cut, he says, was in part to provide "a softer chew" for "younger men." Soon, the company was offering four different Long Cut flavors, including wintergreen.

Last year, the company introduced its even easier-on-the-palate cherry Skoal Long Cut, along with a new spearmint Long Cut flavor. Cherry took off, and is now emerging as the company's most successful new product in about a decade, some distributors say.

The company says it developed cherry "to appeal to adult consumers of other smokeless tobacco products," and notes that there are numerous cherry-flavored tobaccos on the market. It says the launch of both cherry and spearmint was based on research in which more than 60% of adult snuff users said they would purchase the two products. In a brochure, the company describes cherry Skoal's flavor as "fresh-tasting."

But to Kitch Hopkins, a skinny, blond-haired 11-year-old user from New Market, Ala., it "tastes sweet, like a cherry pie." His 17-year-old brother Jackie, lingering outside Bud's Family Arcade, adds, "with cherry, when you swallow, it's more like sweet-tasting bubble gum."

A number of teens interviewed say cherry has become the starter brand of choice among underage users, a group estimated by some government officials to be more than one million strong. Darrell Janke, for example, tried snuff for the first time in the summer of 1993 and, upon entering fifth grade that fall, discovered that "just about everybody" was pulling the same red cans from their back jeans pockets. "Kids are definitely starting out with cherry," says the youngster, who by this summer was buying a can every three days at gas stations in his hometown of St. Maries, Idaho. "The regular kind doesn't taste as good or smell as good—they're aiming this at us."

EVEN SOME FORMER EMPLOYEES have doubts about the company's objectives with cherry. Bob Beets, a sales representative at U.S. Tobacco until 1990, says, "Cherry Skoal is for somebody who likes the taste of candy, if you know what I'm saying."

The new products, and U.S. Tobacco's courtship of beginning users who may move up the line to more potent brands, have paid off: Today, U.S. Tobacco is the most profitable American tobacco company on the basis of profit margins, and controls 84% of the U.S. snuff market. Earlier this year, acclaimed investor Warren Buffett disclosed he had acquired a 2.8% stake in its parent company, which last year earned $349 million on sales of $1.1 billion.

U.S. Tobacco denies that it has a "graduation process" to ratchet users up the line to stronger brands, saying that "there is no set pattern of brand switching." However, the company itself used the term internally, and publicly alluded to it in the mid-1980s. "They talked about graduation all the time—in sales meetings, memos and manuals for the college program. It was a mantra," says Ken Carlsen, a division manager in U.S. Tobacco's sales department, who worked at the company from 1979 until 1986.

"For people who haven't ever tasted [snuff], you'd of course begin them on a product that had a little tobacco taste, but wouldn't turn them off," explains Barry Nova, U.S. Tobacco's president until 1994. He adds: "The graduation is to a more tobacco-y product . . . to a stronger product."

The two recent laboratory tests, conducted by different government agencies, found that U.S. Tobacco's Copenhagen is capable of delivering more nicotine than the company's flavored brands. One analysis, completed last month by the National Institute on Drug Abuse following an inquiry by this newspaper, showed that a one-gram pinch of Copenhagen had an average pH of 8.6, making a huge 79% of its nicotine immediately free for absorption. Cherry Skoal Long Cut posted a pH of 7.5, making 22% of its nicotine immediately free to be absorbed. And in wintergreen Skoal Bandits, with a pH of 6.9, only 7% of its nicotine was instantly available, helping explain why even rookies often complain that this brand is too weak.

The second study, commissioned by the National Cancer Institute and completed in August, came up with similar results. (The two studies found different pH levels for some of the same brands, however; researchers say outside factors, such as how long a product sits on a shelf, also can change a product's pH.)

Jack Henningfield, chief of NIDA's clinical pharmacology branch, contends the research illustrates that U.S. Tobacco's products deliver four different nicotine doses: low, medium, high and super. For those needing a heavy dose, Copenhagen is "the prescription," says the government scientist, who calls this brand "the heroin of smokeless tobacco." U.S. Tobacco says "that claim is without merit," and notes that Mr. Henningfield testified against the company as an expert witness in a 1986 liability trial.

Brian Woodard knows the progression well. Last July, the 14-year-old switched to cherry from popular wintergreen Skoal with the intent of weaning himself off snuff. But by the end of 1993, he was dipping more than ever—and was ready for a "whole new ballgame."

"Cherry kind of prepared me to go all the way up, though I wasn't planning on it preparing me," says the Danville, Ala., youth, who now consumes a can of Copenhagen every day. "Cherry is like the kindergarten for Copenhagen."

According to the Centers for Disease Control and Prevention, snuff users are four times as likely to develop mouth cancer as nonusers. They are 50 times as likely to contract cancers of the gum and inner-cheek lining. Because of exposure to high levels of nicotine and nitrosamines, a chemical linked to cancer, dippers also may suffer tooth loss and gum lesions more frequently than nonusers.

Last year, there were 30,000 new cases of oral cancer in the U.S. and 8,000 deaths. CDC officials believe 75% of the deaths were attributable to cigarette smoking; they don't have figures on the mortality linked to smokeless tobacco.

The statistics don't include people like Sean McFarland, a Fort Worth, Texas, teenager who used to use three cans a week of Copenhagen. Last year, Mr. McFarland was diagnosed with receding gums and hyperkeratosis, or whitish lesions on his lower gums. After a skin-graft operation, the then-18-year-old briefly managed to kick the habit. But three weeks later, he was back to Copenhagen again—though he still had stitches in his mouth and couldn't eat solid food. Today, Mr. McFarland, who now uses five cans a week, has no expectation that he will ever quit.

"Dipping calms me," he says. "It eases me down."

U.S. Tobacco denies that snuff is addictive and disputes the CDC's statistics. It successfully argued that there isn't conclusive evidence linking snuff to cancer in the much-publicized 1986 wrongful-death trial of Sean Marsee. The mother of Mr. Marsee, a 19-year-old Oklahoma "dipper" who died of oral cancer six years after first receiving a free sample of Copenhagen at a rodeo, sued U.S. Tobacco in federal court in Oklahoma City. But the jury took less than a day to absolve the company of liability, and Mrs. Marsee's appeal was unsuccessful.

Negative publicity from the case prompted a 1986 federal law requiring the industry to place health-warning labels on snuff cans. Snuff makers also stopped TV advertising and curbed sampling activities. Yet snuff use among teens by some measures continued to rise, though there are conflicting reports. The CDC reported that 19% of high-school boys had used smokeless tobacco in

1991, up from 2% in 1970. U.S. Tobacco, on the other hand, cites a 1993 report by the Substance Abuse and Mental Health Services Administration saying that the figure had declined to 4.8% of 12- to 17-year-old boys in 1992.

SOME TEENS SAY that U.S. Tobacco's marketing strategies, especially for its cherry Skoal Long Cut, play right to underage users. Though the company spends little on traditional advertising, its full-page ads have appeared recently in magazines including Rolling Stone and Sport. "It's time you got the great taste of Skoal on us," the ads cajoled readers, offering free samples to those who sent in a perforated card. (The ads say the offer isn't available to minors.)

Even more than advertising, U.S. Tobacco spends millions each year doling out free products to woo new dippers, mostly white males from America's blue collar and rural locales, say former employees at Holland Mark Martin, U.S. Tobacco's direct-marketing firm. Consumer-marketing representatives work countless rodeos, car races and fairs. It is here at the grass-roots level that U.S. Tobacco is probably most persuasive: Company sales representatives mix down-home folksiness with a hard sell. Mr. Carlsen, the former division manager, recalls seeing sales representatives "who weren't heavy [snuff] users actually getting sick because they had to keep putting the product in their own mouths."

At a Copenhagen/Skoal Pro Rodeo in New Market, Ala., in late August, a team of U.S. Tobacco's sales reps stood in a green-awninged booth, doling out box after box of cherry and spearmint samples—and sometimes personally demonstrating snuff's appeal—to a steady stream of rodeo fans. Males who asked for it could get wintergreen Skoal Long Cut, and the infrequent female automatically was handed what company representatives billed as "ladylike" Bandits. But the largess had limits: there was nary a sign of either Original Fine Cut Skoal or Copenhagen, which holds a commanding 42% of the snuff market.

That's no mistake, say some veterans of U.S. Tobacco's sales force. They say U.S. Tobacco doesn't want to feed its existing customers—or alienate new ones—with its two most potent products. Snuff is a "tough sell," says Boyd Buergee, a division manager in U.S. Tobacco's sales department until 1987. "You need a product that is mild and good-tasting to get people used to" it.

At the Alabama rodeo, a prominently-placed sign proclaimed: "Absolutely no samples given to those under 19," and company representatives requested identification cards from a number of baby-faced boys. But some teens enlisted older friends or their relatives to stand on line. Others simply fibbed. "I went right up to them and they said, 'Here, have you some cherry,' " bragged 15-year-old Len Cox, triumphantly flashing his samples.

U.S. Tobacco lists numerous steps it takes to prevent youths from procuring its samples. The company's mail-in coupons say that giving false information, such as the wrong age, may be illegal. Samples come in envelopes addressed to the adult head of household. When U.S. Tobacco learns that a youth has falsified his age, he is dropped from its mailing list and a notification letter is sent to an adult resident. Sales representatives must sign a code that samples will be given only to adults.

The company also says it has devoted "substantial resources" to preventing retailers from selling its products to minors. Still, at the XTRA Mart convenience store in Ballston Spa, N.Y., store manager Jacqueline Ketchel contends that any store willing to peddle to minors will sell "tons" of cherry Skoal. Ms. Ketchel, who says she doesn't sell the product to underage users, claims: "With this flavor, the company was shooting for a younger audience just like R.J. Reynolds with Joe Camel."

Already, some of that younger audience says cherry Skoal Long Cut is suffering from a kiddie image; experienced teen dippers insist they have progressed beyond it.

"Doing cherry would make me feel like a wimp," says Marty White, a 15-year-old Copenhagen user in Fort Worth who began his habit at age 11 with Skoal Bandits and says he already has receding gums and mouth sores. Cherry, he adds, "is for little kids." ✣

Climbing the Ladder To More Potent Snuff

COPENHAGEN
The bestselling snuff in America (42% of the market) UST's most potent product ... according to study, contains 11 4 milligrams of nicotine per gram and a high pH level of 8.6 ... 79% of the nicotine is "free," or available for immediate absorption

ORIGINAL FINE CUT SKOAL
About 20% of the snuff market, according to industry estimates UST's second most potent product with 10 4 milligrams of nicotine per gram and a pH of 7 6 . 27% of its nicotine is free ... like Copenhagen, uses a very fine cut of tobacco, which aids nicotine absorption

SKOAL LONG CUT CHERRY
About 3% of the market .. UST's most successful new product in about a decade 11 4 milligrams of nicotine per gram and a pH of 7 5 about 22% of its nicotine is free uses a coarser grade of tobacco, which delivers nicotine more slowly ... cherry flavor makes it seem milder, too

SKOAL BANDITS WINTERGREEN
Less than 2% of the market . . bottom rung of UST's nicotine ladder . 7 5 milligrams of nicotine per gram and a pH of 6 9 ... only 7% of its nicotine is free . comes in a tiny tea-bag-like pouch, so users don't experience direct contact with tobacco

Sources National Institute on Drug Abuse The Maxwell Report industry estimates

Illustrations by Nori Nowak and Nancy Januzzi

The Long Road to Cherry Skoal

WITH ITS POPULAR new cherry Skoal Long Cut, U.S. Tobacco has achieved what once seemed almost impossible: making snuff fashionable, and making it appealing to beginners.

It has been a long road. In the late 1960s, the dipping habit was waning, and snuff was suffering from a decidedly low-brow reputation. With its future hanging in the balance, the UST Inc. unit set out to make snuff and its less savory aspects—like spitting and spittle about the lip line—palatable to a new generation. According to the minutes of a 1968 marketing meeting held in New York, Louis F. Bantle, then vice president for marketing, declared: "We must sell the use of tobacco in the mouth and appeal to young people . . . we hope to start a fad." Mr. Bantle, who followed his father, Louis A. Bantle, as UST's chief executive in 1973 and retired last year, didn't return calls or respond to a letter seeking comment.

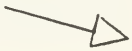
"We were looking for new users—younger people who, by reputation, wouldn't try the old products," recalls meeting attendee James Taft, who later became the company's head of product development.

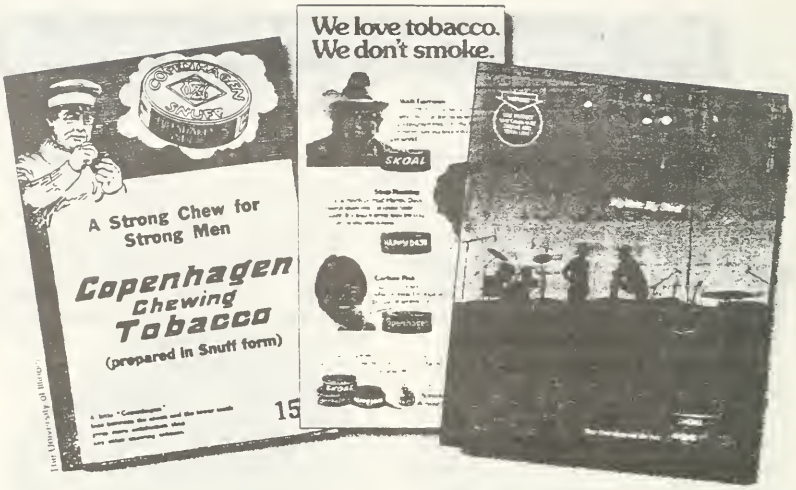
U.S. Tobacco first tackled the development of a starter product, a task that required years of trial and error—often error. In the mid-1960s, for example, the company began marketing Happy Days, which Boston Red Sox catcher Carlton Fisk once touted in ads as "for you guys just starting out."

But Happy Days fell prey to a sissyish image among snuff's macho consumers—an image not helped by its treacly name. "We got a lot of feedback from the field that the name wasn't a hooker name like 'Skoal,' " recalls Thomas O'Grady, who served as UST's vice chairman until 1991. Perhaps an even bigger difficulty, recalls Mr. Taft, was that Happy Days, with flavors including raspberry, was the only U.S. Tobacco snuff product that wasn't fermented. As a result, its pH was "below seven, and too low for nicotine release."

Meanwhile, in an attempt to make snuff more acceptable, the company began using sports stars in ads. In 1973—after cigarette advertising was banned, but snuff advertising was left untouched—it took to the airwaves with ads starring football and rodeo star Walt Garrison. Through the 1970s, Mr. Garrison, who is still on the company's payroll, proclaimed in magazine spreads, "I love tobacco. I don't smoke."

In the early 1980s, endorser and baseball star Bobby Murcer even hit the country-music charts with "I'm a Skoal Dippin' Man." The chorus: "Just a pinch between my cheek and gum . . . makes me feel like a long home run." Mr. Murcer has since quit snuff, and today characterizes himself





Advertisements over the years for U.S. Tobacco's snuff products

as a "huge antitobacco proponent."

Despite those efforts, a rival's starter product began drawing in younger users in a way that U.S. Tobacco's own products weren't. Introduced by Conwood Co. in 1979, the brand was called Hawken. In a memo dated Jan. 21, 1980, A.H. Cameron, one of U.S. Tobacco's regional sales managers, reported this to the firm's national sales manager: "Retailers all agree that the majority of Hawken is being used by young kids and young adults. The age of the kids

is from 9 years old and up." That, the sales manager continued, was "four or five years earlier than we have reached them in the past." (In his testimony during the Marsee trial, Mr. Bantle disputed the young starting age.)

"They were concerned Hawken would appeal to kids because it was sweeter than Original Fine Cut Skoal and used a coarser cut that didn't float as much," recalls Larry Story, who was a company chemist until 1982. U.S. Tobacco also feared, he says, that once initiated to Conwood's starter product, "the Hawken kids might graduate to [Conwood's stronger] Kodiac, rather than to Skoal."

So, as part of the effort to build up its base of young people, U.S. Tobacco in 1983 introduced its Skoal Bandits—a starter product, with the tobacco contained in a pouch like a tea bag, whose name wouldn't make a cowboy cringe.

The brand appeared to have its roots in the Lotus Project, an effort undertaken in the early 1970s by United Scandia International, a joint venture between UST and Swedish Tobacco Co. The mission: "To make it easier for a new user to use tobacco in the mouth," said one of the 1972 marketing documents detailing the project. Its target audience: "New users, mainly cigarette smokers, age group 15 to 35," according to one document.

Joseph Taddeo, U.S. Tobacco's chief executive officer, told Congress in April that this document was "written over 20 years ago, does not mention Skoal Bandits, was not created by U.S. Tobacco and does not reflect U.S. Tobacco policy." The company added in a statement that the document referred only to a marketing initiative in Sweden, by Swedish Tobacco.

The internal document suggests otherwise. According to the document—minutes from a meeting at the company's Greenwich, Conn., headquarters—Louis A. Bantle "declared that he wanted a Lotus product for the U.S. market as soon as possible." Soon after, U.S. Tobacco introduced a snuff product in a tea-bag-like pouch called Good Luck, which ultimately fizzled.

In the end, with Bandits and especially the flavored Skoal Long Cut brands introduced in 1984, U.S. Tobacco appears to have succeeded in making starter products, making them fashionable—and making them lead up the nicotine chain. "A lot of people may start on the more flavored products," says Mr. O'Grady, the former UST vice chairman. "But ultimately, they'll come to Copenhagen."

—Alix M. Freedman

Mr. WAXMAN. Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman.

I also want to share in your remarks to Mr. McMillan, a friend. We have profound differences on the tobacco issue, of course, but he has done yeoman work on many issues, particularly affecting children. And frankly, I am not interested today in convicting anybody or trying any cases, but I do want to talk for a moment about this product and America's children, because the fact is that smokeless tobacco is a health care disaster for the hundreds of thousands of America's kids who use it every day.

Independent scientists and health experts seem unanimous in concluding that smokeless tobacco makes many of our kids sick with disfiguring disease and it sometimes can result in death. I hope that as a result of today's hearing we can provide a strong boost to the cause of deterring America's youngsters from taking up the harmful habit of using snuff and chewing tobacco.

Now, to me, the bottom line here is pretty simple. While control of this committee in the Congress does shift from Democrats to Republicans, the need to protect the health of America's kids is as great as ever. And I hope that in the days ahead Republicans and Democrats in the Congress can work together for common sense public health policies that actually reduce the number of kids using smokeless tobacco products.

I hope Democrats and Republicans, for example, look objectively at the current regulatory system for these products and see how it fails America's youngsters. For example, over the last few weeks, health officials in my home State of Oregon monitored a significant number of randomly selected retail shops across the State. Better than half of these shops were selling tobacco products to underage consumers. Now, we know that there are laws on the books to prevent the sale of tobacco products to minors, but the reality is that they are honored more in the breach than in the observance.

I also hope that Democrats and Republicans acknowledge that smokeless tobacco products that taste like cherry candy are extraordinarily enticing to kids. And I hope that on a bipartisan basis, there can be an effort to discourage the use of these products by kids, through efforts such as restricting access to free samples.

What it all comes down to, Mr. Chairman, is I hope there will be a bipartisan agreement that it is time for some real corporate responsibility to be exercised as far as these products are concerned. I think that protecting America's kids transcends partisanship and I am anxious to work with my colleagues on both sides of the aisle for a bipartisan consensus that zeros in on the health of our children, which, to his credit, has been a special priority of Mr. McMillan during his tenure in Congress. Thank you.

Mr. WAXMAN. Thank you, Mr. Wyden.

Our first witnesses this morning will appear together. Michael Eriksen is director of the Centers for Disease Control's Office on Smoking and Health. Jack Henningfield is chief of Clinical Pharmacology at the National Institute on Drug Abuses's Addiction Research Center. And Gregory Connolly is a dentist and director of the Massachusetts Tobacco Control Program.

As with our practice at all previous oversight hearings on the tobacco issue we are asking that all the witnesses appear under oath.

I want to announce to the three of you that we have the Rules of the House and the Rules Committee at the table with you. They will inform you of the limits on the power of the subcommittee and the extent of your rights during your appearance today.

Do you desire to be represented by counsel or advised by counsel during your appearance today?

Mr. ERIKSEN. No.

Mr. HENNINGFIELD. No.

Mr. CONNOLLY. No.

Mr. WAXMAN. Do you or those you have asked to accompany you object to appearing before this subcommittee under oath?

Mr. ERIKSEN. No.

Mr. HENNINGFIELD. No.

Mr. CONNOLLY. No.

Mr. WAXMAN. If you have no objection to appearing under oath, I would like you to rise, if you would, raise your right hand.

[Witnesses sworn.]

Mr. WAXMAN. Please consider yourself to be under oath.

Please identify yourselves for the record, and include those who are accompanying you as witnesses. And let me just ask, without objection, that your prepared statements be in the record in full. We would like to ask you to limit your oral testimony to around 5 minutes. Why don't you each identify yourself for the record first.

Mr. ERIKSEN. Michael Eriksen, CDC's Office on Smoking and Health.

Mr. HENNINGFIELD. Jack Henningfield, National Institute on Drug Abuse.

Mr. CONNOLLY. Greg Connolly, Massachusetts Department of Public Health.

Mr. WAXMAN. We are pleased to welcome the three of you, and, Dr. Eriksen, why don't you begin.

STATEMENTS OF MICHAEL P. ERIKSEN, DIRECTOR, OFFICE ON SMOKING AND HEALTH, NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, CENTERS FOR DISEASE CONTROL AND PREVENTION; JACK HENNINGFIELD, CHIEF, CLINICAL PHARMACOLOGY BRANCH, ADDICTION RESEARCH CENTER, NATIONAL INSTITUTE ON DRUG ABUSE; AND GREGORY N. CONNOLLY, DIRECTOR, MASSACHUSETTS TOBACCO CONTROL PROGRAM, ON BEHALF OF THE COALITION ON SMOKING AND HEALTH

Mr. ERIKSEN. Good morning, Mr. Chairman, Members of the subcommittee. I am pleased to have this opportunity to address the subcommittee on the use of smokeless tobacco. In my remarks I want to make four points. The first pertains to the recent changes in the pattern of smokeless tobacco use; the second, current estimates of use; the third, brand preference; and, fourth, reasons for smokeless tobacco use and difficulties in quitting.

Before addressing these four specific issues, I would like to state unequivocally that smokeless tobacco use is a health hazard and it is not a safe alternative to smoking. Primary adverse health effects of smokeless tobacco include oral cancer, leukoplakia, gingival recession, and nicotine addiction.

My first point pertains to patterns of smokeless tobacco use. And during the past 25 years there has been a dramatic shift in who uses smokeless tobacco in this country. In 1970, the use of smokeless tobacco was a behavior primarily restricted to older men, both black and white. For example, in 1970, 12.7 percent of men 65 years of age and older were current users of smokeless tobacco. In 1991, the rate had gone down to 5.6 percent, a reduction of over half. During the same time period, however, smokeless tobacco use among young men 18 to 24 years old increased from 2.2 percent in 1970 to 8.4 percent in 1991, an increase of nearly 300 percent. When looking at changes by race, since 1970, black men of all ages have decreased their use, while use among white men aged 18 to 24 years increased nearly fivefold. Today, over 10 percent of young, white men 18 to 24 years old in this country are current smokeless tobacco users.

So my first point is that since 1970, the epidemiology of smokeless tobacco use has virtually reversed itself. No longer is smokeless tobacco a habit of older men. The highest use now occurs among young white men, who increasingly choose moist snuff products.

My second point pertains to the current estimates of smokeless tobacco for young people. As I just said, for 18 to 24 year olds, the current rate is 8.4 percent. The question becomes what is the rate for 12 to 17 year olds? The Healthy People 2000 target is 4 percent for this age group.

Some data suggests that the rate may be approaching that. Data from the Substance Abuse and Mental Health Services Administration's National Household Survey on Drug Abuse suggests a 1992 rate of 4.8 percent among this age group, very close to the year 2000 target. However, other Federal surveys are in stark contrast to this.

For example, NIDA's Monitoring the Future Survey, has a rate of 19.7 percent among male high school seniors. CDC's school-based youth risk behavior survey estimates 19.2 percent for male 9th to 12th graders. This compares to the previous household survey that I mentioned of 4.8 percent, which is done in the home and is on males 12 to 17, which includes the youngest boys.

The question becomes why is there such great variation in these surveys? Part of the reason may be is that the tobacco questions are asked verbally in the home that gets the lowest estimates.

To compare asking the same questions to the same age children in the same setting, we analyzed 1992 household YRBS data for males 12 to 17. And this corresponds precisely to the national household survey that had the 4.8 percent. When we did that, we found that smokeless tobacco prevalence was 11.9 percent among 12- to 17-year-old males, nearly triple the rate previously seen.

We cannot entirely explain these large differences in the same types of household surveys, but we think part of it may be this YRBS survey uses a very innovative methodology where they put headphones on the teenager who listens to a tape and is able to respond totally confidentially and has no fear of his parents hearing the responses. And we think that this type of assessment provides greater accuracy, and may account for some of the differences between the studies.

So my second point is that there is wide variation of estimates ranging from 4 percent to 12 percent for 12- to 17-year-old boys. Because of this, we continue to be concerned that we may not be able to reach our year 2000 objective of 4 percent.

My third point pertains to brand preference. To understand which brands of smokeless teens used, we analyzed the Teenage Attitudes and Practice Survey which was done in 1993 on kids 10 to 22 years old. Analysis of this data revealed that Skoal Bandits was the preferred brand for over 5 percent of young users. This far exceeds the 1 to 2 percent market share Skoal Bandits enjoy overall. The smokeless tobacco used in Skoal Bandits is contained in tea-like pouches, thus avoiding direct contact between the tobacco and the skin.

We were also able to determine which brands young people used first and which brands they used after a few years of regular use. We found that during the first year of using smokeless tobacco, Copenhagen, the most popular brand overall, was the brand of choice for only 13 percent of young people. However, after 4 years of use, 43 percent of young people chose Copenhagen. So over time, the increase went from 13 percent to 43 percent use of Copenhagen. So my third point is that evidence suggests that new smokeless tobacco users prefer the flavored, easy-to-use products, and these are the very products that are experiencing increasing market share.

My last point pertains to difficulties in quitting and why kids use smokeless tobacco. We found that the greater the level of use of the tobacco product, whether it's cigarettes or smokeless, the more likely the young people are to report that they continue to use a product because "it relaxes or calms me," or "because it's really hard to quit." And that this dose-response relationship between exposure and reasons for use held true for cigarettes and smokeless tobacco for the youngest teens and the oldest teens.

For example, 74 percent of young people who use smokeless tobacco every day report that it's really hard to quit, compared to only 11 percent who used smokeless tobacco 1 to 14 days a month. When looking at it by brand, 22 percent of infrequent Copenhagen users reported that it's really hard to quit, compared to 7 percent of infrequent Skoal users, suggesting a greater psychopharmacological effect from Copenhagen.

Similar dose-response relationships were observed when young people described their symptoms when attempting to quit using smokeless tobacco. Over 90 percent of daily smokeless tobacco users reported at least one symptom of nicotine withdrawal when trying to discontinue use. A strong urge or need to use the product and increased irritability were the most common symptoms reported.

The summary for my final point is that young people become addicted to smokeless tobacco the same way that young people become addicted to cigarettes, which is the same way that adults become addicted to tobacco products. Simply put, the greater the exposure, the more likely young people report it's really hard to quit and will experience withdrawal symptoms when they try.

In conclusion, I want to emphasize that the use of smokeless tobacco is a significant health hazard and causes a variety of health problems, including oral cancer. I also want to reiterate my four

major points: One, that primary users of smokeless tobacco are now young people; second, there is good evidence to suggest that we will not reach our year 2000 objective at the course we're taking now; third, young people who use smokeless tobacco prefer flavored and easy-to-use products, which are becoming an increasing large part of the market; and, fourth, young people become addicted to smokeless tobacco in direct proportion to their use of the product, and nearly all report symptoms of nicotine withdrawal when they try to quit.

Thank you for the opportunity to present this information. I would be pleased to answer any questions you may have.

[The prepared statement of Dr. Eriksen follows:]

Testimony of

Michael P. Eriksen, Sc.D.

Good morning, Mr. Chairman and members of the Subcommittee. I am Michael Eriksen, Director of the Centers for Disease Control and Prevention's Office on Smoking and Health. I am pleased to have this opportunity to address the Subcommittee on the use of smokeless tobacco in this country, particularly among young people. In my remarks I will describe 1) recent changes in the pattern of smokeless tobacco use, 2) current estimates of smokeless tobacco use, particularly in relation to the national Healthy People 2000 objectives, 3) brand preference of smokeless tobacco products and relationship to nicotine addiction, and 4) reasons for smokeless tobacco use and difficulties in quitting. For each of these four points, I will place special emphasis on the data as they relate to young people. However, before addressing these four specific points, I would like to state unequivocally that smokeless tobacco use is a health hazard and it is not a safe alternative to smoking. The primary adverse health effects of smokeless tobacco include oral cancer, leukoplakia, gingival recession, and nicotine addiction. In one study, for example, long-term users of snuff were 48 times more likely than non-users to develop cancers of the gingiva (gums) and buccal mucosa (cheek). Another study found that compared with non-users, persons chewing tobacco were six times more likely to develop cancer of the oral cavity or the hypopharynx and three times more likely to develop cancer of the oropharynx. And a recent report has linked smokeless tobacco use with an increased risk of cardiovascular mortality.

Recent Changes in the Pattern of Smokeless Tobacco Use

During the last 25 years, there has been a dramatic shift in who the users are of smokeless tobacco. In 1970, the use of smokeless tobacco was a behavior primarily restricted to older men, both black and white, and older black women. For example, in 1970, 12.7% of men 65 years of age and older were current users of smokeless tobacco. By 1991, among older men, the rate of use had dropped to 5.6%, a reduction of 56%. During this same period, however, smokeless tobacco use among young men 18-24 years old increased from 2.2% in 1970 to 8.4% in 1991, an increase of nearly 300%. When looking at changes by race since 1970, black men of all ages decreased their use of smokeless tobacco, while use among white men aged 18-24 years increased nearly five-fold. Today, over 10% of young, white men (18-24 years old) in this country are current smokeless tobacco users.

Following this shift in smokeless tobacco use from older men to primarily young white men, there has been a net increase in the use of smokeless tobacco, particularly for moist snuff, the type of smokeless tobacco preferred by young men. According to the U.S. Department of Agriculture, snuff is the only tobacco product for which per capita consumption has actually increased since 1981, now amounting to over 61 million pounds being produced annually, or about one-third of a pound for every man and woman in this country.

Since 1970, the epidemiology of smokeless tobacco use has virtually reversed itself. No longer is smokeless tobacco a habit of older men; the highest use now occurs among young white men who increasingly choose moist snuff products.

Current Estimates of Smokeless Tobacco Use In Relation to the Healthy People 2000 Objectives

The Healthy People 2000 objective for smokeless tobacco use for males 12-24 years of age is to achieve a prevalence of use of no more than 4% by the Year 2000. In my previous comments, I indicated that, as of 1991, smokeless tobacco use among males 18-24 was 8.4%, nearly double the Healthy People 2000 objective of 4%. The question now becomes what is the smokeless tobacco prevalence among 12-17 year-old males.

It has been suggested that rates are falling and that we are approaching the Healthy People 2000 target of 4%. Data from the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Household Survey on Drug Abuse (NHSDA) suggest a 1992 smokeless tobacco rate of 4.8% among this age group, very close to the Healthy People 2000 target. Preliminary data from this report for 1993 suggest that this rate may actually be even lower (3.9%). These estimates, however, are much lower than those of other Federal surveys which collect similar data on slightly different age groups. The National Institute on Drug Abuse's (NIDA) 1993 Monitoring the Future Survey estimates smokeless tobacco prevalence of 19.7% for male high school seniors. CDC's school-based Youth Risk Behavior Survey (YRBS) estimates a 19.2% rate for male ninth to twelfth graders for 1991. While these rates are dramatically higher than the 4.8% estimate from the NHSDA (which is the data source used to monitor the Healthy People 2000 objectives), each survey uses slightly different age groups and collects data in different ways.

The estimate from NIDA's Monitoring the Future Survey of 19.7% is collected in schools and is for male high school seniors (17-18 year olds); the school-based YRBS estimate of 19.2% is for male ninth to twelfth graders (14-18 year olds); and the NHSDA estimate of 4.8% is collected at home and is for male, 12-17 year olds, clearly including the youngest boys of any of the surveys.

To compare same-age children in the same setting, we analyzed the 1992 household-based YRBS for male 12-17 year olds (to correspond precisely to the household setting and the specific age group in the NHSDA). In doing so, we found a smokeless tobacco prevalence rate of 11.9% or nearly three times the Healthy People 2000 objective.

While we cannot completely explain the reason for the large differences in estimates using data from household surveys for the same age children, we believe that part of the difference may be attributable to underreporting in household surveys when teenage respondents are in "earshot" of their parents. The household-based YRBS, with the higher estimate of 11.9%, may have overcome this underreporting bias by using a sophisticated methodology that allows a teenage respondent to listen to the survey questions privately through earphones connected to a cassette tape recorder and then complete a coded answer sheet.

This innovative method of assessing teen risk behaviors may provide greater accuracy and may account for some of the difference between the estimates. Similarly, part of the reason school surveys give higher estimates may be the anonymity afforded to respondents.

Because of the wide variation of estimates of smokeless tobacco use among teenagers, ranging from about 4% to 12% for 12-17 year old boys, we continue to be concerned that we will not reach the Healthy People 2000 objective of reducing smokeless tobacco use to a rate of no more than 4%.

Brand Preferences of Smokeless Tobacco Products

As the use of smokeless tobacco shifted from the older male to the younger male, there was a corresponding shift from chewing tobacco to snuff, particularly to moist snuff and fine cut, of which the U.S. Tobacco Company has 84% of the market.

The issue of brand preference of snuff among adolescents is important because of the relationship between the level of nicotine bioavailability in snuff and patterns of use by adolescents. A recent Wall Street Journal article maintains that the availability of nicotine can vary among brands by an order of magnitude that is by a factor of 10 -- with "beginner" brands having far less nicotine available.

To understand which snuff brands teens prefer, we analyzed data from CDC's second Teenage Attitudes and Practices Survey (TAPS), a longitudinal survey conducted in 1993 of nearly 13,000 young people aged 10-22. Analysis of these data revealed that Skoal Bandits was the preferred brand for over 5% of young people, far exceeding the 1% to 2% market share Skoal Bandits enjoys overall. The smokeless tobacco used in Skoal Bandits is contained in tea-bag-like pouches, thus avoiding direct contact between the tobacco and the skin and, for this reason, is widely regarded as a "starter" product.

We were also able to determine which brands young people used first, and which brands they used after a few years of regular use. We found that during the first year of using smokeless tobacco, Copenhagen, the most popular brand and the brand with the most nicotine bioavailability, was the brand of choice for only 13% of young people. However, for young people who have used smokeless tobacco for four or more years, 43% chose Copenhagen. These data suggest that young people tend to begin their smokeless tobacco use with those brands that are less harsh, often-flavored, and easy-to-use. After a few years of experience, young users then prefer brands with more nicotine bioavailability.

It is important to note that between 1992 and 1993 there was a significant shift in moist snuff market share with a 5 % point drop in Copenhagen and corresponding increases in Skoal and Skoal Bandit. The 1993 Maxwell Tobacco Fact Book, a tobacco industry trade journal, observes:

"At UST [U.S. Tobacco Company], declines in Copenhagen were

more than offset by strong volume increases in Skoal, crediting the introduction of Skoal cherry and spearmint and an increase in Skoal Bandits (p 27)."

Emerging evidence exists that new smokeless tobacco users prefer the flavored, easy-to-use products and these are the very products that are experiencing increasing market share.

Difficulties Young People Experience in Trying to Quit

Last month we released 1993 TAPS data on reasons why young people continue to smoke and use smokeless tobacco and the difficulties they experience when they try to quit. We found that the greater the level of use of the tobacco product, the more likely young people are to report that they continue to use the product because "it relaxes or calms me" or because "it's really hard to quit."

This dose-response relationship between exposure and reasons for using held true for both cigarettes and smokeless tobacco, for the youngest (10 - 18 years) and the oldest (19 - 22 years) age groups and for all measures of exposure (lifetime use, frequency of use per month, and intensity of use per day). For example, 74% of young people who use smokeless tobacco every day reported that "its really hard to quit" compared to only 11% of those who used smokeless tobacco 1-14 days a month. When looked at by brand, 22% of infrequent (1-14 days) Copenhagen users reported that "it's really hard to quit" compared to 7% of infrequent Skoal or Skoal Bandit users, suggesting a greater psychopharmacologic effect from Copenhagen.

Similar dose-response relationships were observed when young people described their symptoms when attempting to quit using smokeless tobacco. Over 90% of daily smokeless tobacco users reported at least one symptom of nicotine withdrawal when trying to discontinue use. A strong urge or need to use the product and increased irritability were the most common symptoms reported. Interestingly, 70% of infrequent (1-14 days/month) Copenhagen users who quit or had tried to quit reported at least one symptom of nicotine withdrawal compared to less than 25% of infrequent Skoal and Skoal Bandit users, again suggesting that Copenhagen delivers a higher dose of nicotine, making quitting more difficult.

Young people become addicted to smokeless tobacco the same way that young people become addicted to cigarettes which is the same way that adults become addicted to tobacco products. Simply put, the greater the exposure, the more likely young people will report that "it's really hard to quit" and will experience withdrawal symptoms when they try.

In conclusion, I want to emphasize that the use of smokeless tobacco is a significant health hazard and causes a variety of health problems, including oral cancer. I also want to reiterate my four major points: 1) the primary users of smokeless tobacco are now young people, 2) there is good evidence to suggest that we will not reach the Year 2000 objective of no more than 4% prevalence for either young adult or teenage males, 3) young people who use smokeless tobacco disproportionately prefer flavored and easy-to-use products which are experiencing an increase in market share; and 4) young people become addicted to smokeless tobacco in direct proportion to their use of the product and nearly all report symptoms of nicotine withdrawal when they try to quit.

Thank you for the opportunity to present this information and I would be pleased to answer any questions that you may have.

Mr. WAXMAN. Thank you very much, Dr. Eriksen. We are going to have some questions but I want to hear from the other two witnesses.

Dr. Henningfield.

STATEMENT OF JACK HENNINGFIELD

Mr. HENNINGFIELD. Good morning. I am pleased to testify before you today, Mr. Chairman and Members of the committee. My comments will describe the results of tests on the nicotine dosing capacity of six smokeless tobacco products.

Mr. Chairman, as Dr. Eriksen has just stated, smokeless tobacco use increased dramatically among male adolescents in the United States in the 1970's and 1980's. Of particular interest to NIDA is that it has been shown that smokeless tobacco use, users, are more likely to smoke cigarettes and to abuse alcohol and illicit drugs than nonsmokeless users.

NIDA has been studying nicotine for more than 15 years. Nicotine is a convenient drug to study because it is legal and widely used, yet it has the features of a prototypic addictive drug in that it is psychoactive, produces tolerance, physical dependence, and reinforcement.

Nicotine dosage of smokeless tobacco products is primarily controlled by three factors: The nicotine content of the product, the pH level of the product, and the cut of the tobacco fiber or the particle. One manufacturer took dosage control one step further by placing unit doses in small pouches. Other factors, such as chemicals that coat tobacco fibers and affect the way the fibers stick together, could also affect nicotine dose to humans.

All other things being equal, the pH level is the gatekeeper of nicotine release to humans. PH is related to how much nicotine is free to be absorbed to humans. PH is measured on a scale from 0 to 14, with 7 being neutral, and lower numbers being acid, higher numbers being alkaline. When pH is below 7, most of the nicotine molecules are in an ionized or electrically charged state. Essentially this produces an electrical barrier that prevents the nicotine from being rapidly absorbed by humans.

Without knowing pH levels, nicotine content is of little use in predicting what a human would get over time when they used a nicotine product in the mouth. For example, the mildly alkaline smoke of pipes and cigars in which pH is generally 7.5 or greater is well absorbed in the mouth. The user does not have to inhale to obtain nicotine from these products. On the other hand, cigarette smoke is somewhat acidic and people have to inhale nicotine into the lungs to get effective absorption.

To determine how nicotine content and pH vary among a series of smokeless tobacco products, and if nicotine dose was controlled selectively, we performed a series of tests at the Addiction Research Center to estimate the free nicotine dosing capability of these products.

Products were selected to reflect a cross-section of those from the company which supplies approximately 85 percent of the U.S. moist snuff market and products which are very widely available across the United States. We obtained six brands from four different loca-

tions in Baltimore City, a Baltimore suburb; Lansing, Michigan; and Boston, Massachusetts.

Our results indicated that a wide range of pH levels exist across the smokeless tobacco products. This results in alteration in the amount of nicotine that is available to be absorbed and would ultimately determine the actual dose of nicotine delivered to the user. We also found differences in tobacco cut and consistency, which was consistent with product labels, such as "long cut" versus "fine cut."

I would like to show you a figure, please. We found that nicotine concentrations of one product, the product labeled A, were quite low at 7.5 milligrams nicotine per gram of wet or undried tobacco. For the other products, the nicotine content was in the area of 10.3 to 11.4 milligrams per gram tobacco. The pH levels varied quite widely in 6.9 to 8.6. The figure shows the consequences of this pH difference on the actual nicotine dosing capability. This was estimated using what is called the Henderson-Hasselbalch equation, which allows one to predict free nicotine or other chemicals that are free that follow such rules, such as cocaine.

Products A through F, vary enormously in pH, and, thus also vary enormously in free nicotine, with product A having a free nicotine in the range of about 7 percent and with product F having free nicotine in the range of 79 percent. So there is more than a tenfold dosing capability range.

Now, as I mentioned, other factors that delay the release of nicotine from the tobacco itself, such as larger tobacco cuttings, chemical coatings, and possibly the pouch used to encapsulate the tobacco from one product, might also affect free nicotine. To precisely predict human doses obtained, it would be necessary to actually do human bioavailability studies. These are the kinds of tests that FDA routinely has drug manufacturers do to take into account factors in humans that may alter the predicted dosing capabilities of drug delivering products. However, our data leave no question that these products vary widely in their nicotine dosing capacity. Thus, while it is possible to rank order the products on the basis of their dosing characteristics, human bioavailability testing would be needed to determine the actual time course and amount of nicotine that would be absorbed from each of these products.

We can conclude from these data that nicotine dosing capacity varies from product to product, and is determined by the nicotine content and the pH of the product. Our data do not address the means by which pH levels vary. However, it is important to note that pH levels over the range observed in our study would not be expected to occur naturally in tobacco.

Our data provide no information on the processes used to control pH or the intent of such manipulations. Changes in pH, however, appear to be the primary means by which nicotine dosage capacity would vary across products. Bioavailability testing, that is actually putting the product in people and measuring the appearance in the blood of nicotine, would be required to determine the actual amounts of nicotine that a user would obtain from each product.

Thank you for the opportunity to present the results of our study. I will be happy to answer any questions.

[The prepared statement of Dr. Henningfield follows:]

STATEMENT BY

JACK HENNINGFIELD, PH.D.

I am pleased to testify before you today, Mr. Chairman, and to have the opportunity to participate in this hearing on smokeless tobacco products such as snuff and chewing tobacco. I am Dr. Jack Henningfield, a research pharmacologist and Chief of the Clinical Pharmacology Branch at the Addiction Research Center of the National Institute on Drug Abuse (NIDA), National Institutes of Health.

Mr. Chairman, smokeless tobacco use increased among male adolescents in the United States in the 1970's and 1980's. Among 17-19 year olds, only 1.5 percent of males reported "current use" (past 30 days) of either snuff or chewing tobacco in 1970; by 1986, 9.8 percent were using at least one of these smokeless tobacco forms. In 1993, the Monitoring the Future Survey showed that 19.7 percent of male high school seniors had reported using smokeless tobacco during the past 30 days. The 1993 National Household Survey on Drug Abuse found 6.1 million current smokeless tobacco users nationwide.

These statistics are of grave concern because research indicates that smokeless tobacco is a cause of oral cancers as well as other diseases. Additionally, and of particular interest to NIDA, it has been shown that smokeless tobacco users are more likely to smoke cigarettes and abuse alcohol and illicit drugs than non-smokeless users. NIDA has been studying nicotine for more than 15 years. Nicotine is a convenient drug to study because it is legal and widely used, yet has the features of prototypic addictive drugs in that it is psychoactive, and produces tolerance, physical dependence and reinforcement.

Nicotine dosage of smokeless tobacco products is primarily controlled by three factors: adjusting the concentration of nicotine in the tobacco product; controlling the pH level (acidity or alkalinity) of the product; and adjusting the size of the tobacco fibers or particles. One manufacturer took dosage control one step further by placing one-half gram of tobacco in enclosed pouches so that unit dosage was controlled. Other factors, such as chemicals that coat the tobacco fibers or bind them together also might influence the speed of release of nicotine from the tobacco.

All other things being equal, the pH level determines how much nicotine from tobacco is immediately free to be absorbed; pH values express acidity or alkalinity on a scale whose values run from 0 to 14, with 7 representing neutrality. Numbers less than 7 show increasing acidity, and numbers greater than 7 increasing alkalinity. When the pH is below 7, most of the nicotine molecules are in an "ionized" state and cannot be absorbed. Only un-ionized or "free" nicotine can be absorbed in the mouth. Because nicotine is a small molecule that dissolves in both water and lipid solutions, as pH levels rise, nicotine molecules can very quickly cross membranes of the skin in the free form.

To elaborate, when smokeless tobacco is placed in the mouth, nicotine is released from the surface of the tobacco fiber into the general saliva of the mouth or directly to the buccal or nasal mucosa. Upon release, nicotine must then be transferred across the oral mucosa to be absorbed into the blood stream. The speed of transfer and amount of nicotine absorption is limited by the availability of un-ionized nicotine. Very high concentrations of nicotine base (un-ionized) will result in biologically significant levels being absorbed very quickly.

However, if the amount of un-ionized nicotine is low the rate of absorption will be greatly diminished. Since only free nicotine (or un-ionized nicotine) can readily penetrate biological membranes, ionized nicotine is essentially trapped on one side of the membrane (i.e., inside the mouth) and remains there until swallowed or until the pH rises to liberate free nicotine.

There are few published studies on the actual dosing capabilities of smokeless tobacco products. A recent study reported the nicotine concentrations of several products but did not report the pH levels. Without pH levels, nicotine content is of little value in comparing nicotine bioavailability across products.

For the reasons just stated, pH is a crucial determinant of nicotine absorption through the nose and mouth. Thus, the mildly alkaline smoke of pipe and cigar tobacco in which the pH is frequently 7.5 or greater, is well absorbed through the nose and mouth. In contrast, the smoke of flue-cured cigarette tobacco, is mildly acidic with values ranging from 5.5 to 6.0 and is poorly absorbed through the nose and mouth and must be inhaled to provide efficient absorption. Once inhaled into the lungs, pH is less important and nicotine is rapidly absorbed and distributed throughout the body.

To determine if nicotine content and pH vary among a series of smokeless tobacco products and if nicotine dosage would be altered selectively, NIDA's Addiction Research Center performed tests to evaluate the pH levels and nicotine concentrations of several smokeless tobacco products, and thereby provide a means of estimating the amount of free nicotine available for absorption. Free un-ionized nicotine, available for absorption from each product was estimated mathematically using the Henderson-Hasselbalch equation.

Products were selected to reflect a cross-section of those from the tobacco company which supplies approximately 85% of the U.S. moist snuff market. Six smokeless tobacco brands were

purchased from four locations: Baltimore City, Maryland; Baltimore County Maryland; Lansing, Michigan; and Boston, Massachusetts.

The results of this study indicate that a wide range of pH levels exists across the six smokeless tobacco products tested. This results in alteration of the amount of nicotine available for absorption and ultimately determines the dose of nicotine delivered to the user. Visual inspection also revealed obvious differences in tobacco cut and consistency in accordance with product labels, e.g., "Long Cut" versus "Fine Cut."

As you can see from the Figure, the nicotine concentrations of the tobacco products range from a low of 7.5 mg nicotine per gram of wet (undried) tobacco, to 11.4 mg per gram. The pH levels ranged from 6.9 to 8.6. These data enabled the identification of four levels of available nicotine across products with free nicotine estimates ranging widely from a low of 7 percent to a high of 79 percent.

A factor that was considered to be important in differentiating product E from products B, C, and D, was the size and consistency of the tobacco particles. Tobacco fibers of products B, C, and D, are approximately 0.4 cm in length and tend to stick together in clusters, apparently due to the adhesive quality of the flavorings and other additives. By contrast, product E had the appearance and consistency of a coarse powder, and would thus provide much greater tobacco surface area per gram of tobacco. These characteristics could result in the nicotine being much more slowly released from the products with long cut fibers compared to products with fine cut tobacco.

When considering the estimated nicotine delivery values across products, it is important to note that several factors could influence the actual amount of nicotine absorbed. For example, the comparative calculations used in Figure 1 are based on 1 gram of tobacco but smokeless tobacco is used in doses

commonly ranging from 0.5 to close to 2 grams. Additionally, the pH of the products might be modifiable by the buffers contained in saliva.

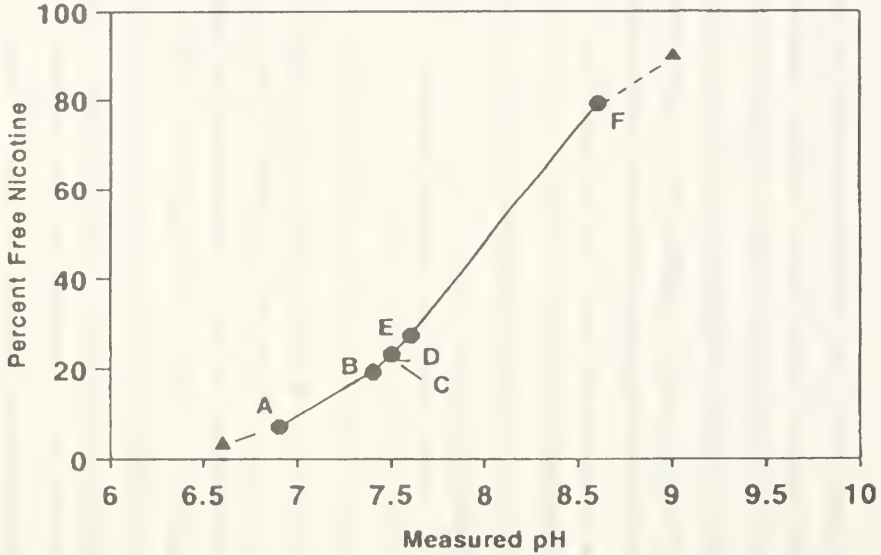
Other factors that delay the release of nicotine from the tobacco itself, such as larger tobacco cuttings, chemical coatings, and possibly the pouch used to encapsulate tobacco in some products, could also modulate the speed of nicotine absorption. Our data leave no question that these products vary widely in their dosing capabilities; we just cannot predict from our data the precise blood levels that would be produced. Thus, while it is possible to rank order products on the basis of their dosing characteristics, human bioavailability testing must be conducted to determine actual time course and amount of nicotine that would be absorbed from each of these products.

Conclusion:

We can conclude from these data that nicotine dose varies from product to product and is determined by the nicotine content and pH of the product. Our data do not address the means by which pH levels vary; however, it is important to note that pH levels over the range observed in our study would not be expected in naturally occurring tobacco. Our data provide no information on the processes used to control pH level. One report suggested that sodium carbonate and ammonium carbonate are added to increase the pH of the otherwise acidic tobaccos used to produce these smokeless tobacco products. Changes in pH appear to be the primary means of varying nicotine dosage. Bioavailability testing would be required to determine actual amounts of nicotine absorbed per gram of the various products and to determine the influence of factors such as tobacco cut and other chemical additives.

Again, I thank you for the opportunity to present the results of this study. I would be happy to answer any questions you may have.

Free Nicotine as a Function of Tobacco pH



Calculated proportion of bioavailable or "free nicotine", based on the pH measured for each product, as calculated using the Henderson-Hasselbalch equation
Triangles indicate free nicotine levels at pH values of 6.6 or 9.0

Mr. WAXMAN. Thank you very much, Dr. Henningfield.
Dr. Connolly.

STATEMENT OF GREGORY N. CONNOLLY

Mr. CONNOLLY. Thank you, Mr. Chairman. Being a baseball fan, I like to play cleanup on this panel.

I am here today because we have a silent epidemic in this country, and that's use of smokeless tobacco by teenagers throughout the United States of America. This problem is not an accident. It's a result of a manufacturer intentionally developing starter low nicotine brands and marketing those brands to young people.

Could I have the first chart, if you could please flip it over?

The first chart shows oral snuff use in 1970. The highest cohort was elderly men, ages 50 plus. If you look at that chart, as a public health official you don't get worried, they're going to die soon, enjoy their tobacco and probably not collect social security.

The chart below, it looks at 1991, just the 18 through 19. It shows 7.8 percent use rate among teenagers. That chart represents a ticking time bomb in the mouths of millions of American children in this country.

And going to Major League baseball, the opportunity to go to the parks with the National Cancer Institute, I look in the mouths of the baseball players and see lesions in their mouths. They can't quit because they're hooked on Copenhagen. They started on Skoal Bandits. They've been enticed and induced to become role models for even younger people.

Next chart, please. We've had the opportunity since the last hearing to collect evidence with the American Health Foundation on nicotine bioavailability. This is a chart that came from the Marsee court case, it's United States Tobacco Company court document, that says they have a graduation process. Mr. Taddeo denied this. This is his own company's document. I'm surprised that he would misrepresent his own company in this way.

At the bottom of the chart they have Skoal Bandits, and the research we've done at the American Health Foundation shows that because the adjustment of the pH, the low pH, only a very small portion of nicotine is released to the Bandit.

Next, we have Skoal Long Cut, and with the research it shows about 22 percent. And if the committee would like to smell this, it smells like children's cough medicine. If you could pass it around.

Next, with the graduation strategy, we go up to Skoal, which is about 30 percent free nicotine.

Finally, we go to Copenhagen. And the most disturbing part with the Copenhagen is the Copenhagen is not only rich in nicotine, an addictive substance, but because of the fermentation process it's extremely high in cancer causing nitrosamines.

Mr. Chairman, I'm not anti tobacco. I'm anti cancer. If this product here—you'd have to dry a truck full of bacon to get the same level of nitrosamines in the truck full of bacon, because the Congress in its wisdom has regulated bacon, baby bottle nipples, and beer, but we haven't regulated tobacco products.

Next chart, please. The tobacco industry says they don't market and advertise. You just have to look at this advertisement for Skoal

Bandits, introducing, easy to use, smooth, convenient, anywhere, any time.

Next chart please. There's instructions how to use the Skoal Bandit; instructions are, how long should I keep the pouch in my mouth? If you haven't tried Skoal Bandits before, we recommend that you keep one for about a minute, then remove. The next time, leave it in a little bit longer, just like your first beer. That's teaching nonusers how to develop tolerance to the toxic effects of nicotine.

And if that message doesn't get through, next chart, please, you can look at the ad, please flip that over, for Copenhagen. And all it says there is, sooner or later it's Copenhagen. Mr. Taddeo denied having a graduation strategy.

Next chart, please. This is from a Danish oral snuff manufacturer. He sells Oliver Twist in the United States, with light to heavy strength. If you look at the top, we have freshmen, with the taste of light and fresh anisette, perfect for beginners. At the bottom, we have bitter, large size rolls with the seasoned flavor and the dark fired taste of tobacco for senior connoisseurs and experienced smokers.

Give me a break, Mr. Chairman. Swedish Tobacco Company readily admits they put additives to free up nicotine. According to Swedish Tobacco Company's fact sheet, which manufactures oral snuff, sodium carbonate, which is an active ingredient increasing the pH, which makes nicotine more easily released from the tobacco and subsequently facilitates the uptake of the nicotine through the mucus membranes of the mouth. This is what the Swedish Tobacco Company says to the United States Congress.

Why can't the United States Tobacco Company say the same thing to the United States Congress? Why does the Danish tobacco company say what the facts are to the United States Congress but our own United States Tobacco Company can't tell the young people in America what they're really up to?

Just flip that over, please. Well, if you want to find what they're up to, one only has to look at the court records from the Marsee court case. These were documents that were not entered but statements read from Mr. Bantle from the documents. This is United States Tobacco Company, graduation theory: New users of smokeless tobacco attracted to the category for a variety of reasons. After a period of time, there's a natural progression of product switching that a full bodied, more flavored—this brand, Happy Days, the perfect starter brand, has been clearly positioned as a starter product, increased the kick, which refers to nicotine.

Next chart, please. Flavor-wise, we should try for innovation, taste, and strength. Nicotine should be medium, recognizing the fact that virtually all tobacco use is based upon nicotine, the kick, the satisfaction. Skoal Bandits will continue to fuel the new user base to assure graduation to our priority moist brand.

Next chart, please. Product graduation process, the smokeless consumer market representative must be aware of the importance of developing new users and the importance of developing the graduation sampling brands. Sampling Skoal Bandits often intensively enter around the retail account to greet new customers and feed the graduation process.

Next chart, please. I won't take any more time of the committee. The bottom is from an adage where Mr. Nova, President of U.S. Tobacco, stated in 1983, aside from appealing to smokers, the new product is designed to hook consumers into what Mr. Nova, President, UST, calls graduation process, from Bandits to Skoal itself, then to Copenhagen, the company's strongest chewing tobacco.

These are the facts, Mr. Chairman. Those are not my facts. Those are facts of the United States Tobacco Company that they refuse to give to this committee. The tragedy is, is that the people that become victim of these are teenagers that don't know any better, that experiment, that go on to become addicted to the product. And if one thing they deserve, and one thing only, that's the truth.

Thank you very much, Mr. Chairman.

[The prepared statement of Dr. Connolly follows:]

Statement of the

Coalition on Smoking or Health

by

Gregory N. Connolly, D.M.D.,M.P.H.

My name is Gregory N. Connolly I am a dentist and public health official with the Massachusetts Department of Public Health and serve as the Director of the Tobacco Control Program. I am testifying on behalf of the Coalition on Smoking or Health. Oral snuff is a finely cut processed tobacco which the user places between the cheek and gums. In 1986 the Surgeon General[1] concluded that use of these products cause oral cancer, gum disease and nicotine addiction. More recent research suggests that snuff increases risk to cardiovascular disease including heart attack. In recent years use of oral snuff has risen dramatically among young males. From 1970 to 1991, the prevalence of use of snuff by men 18+ rose from 1.4% to 3.1% and among males 18-19 from .3% in 1970 to 7.6% making that age group the heaviest users of the product (see Appendix A). The 1990 Youth Risk Behavior Survey found that 24 percent of all white male high school students use smokeless tobacco ar least once during the past month.[2] A 1989 National Collegiate Athletic Association (NCAA) survey of college athletes found a 40 percent increase (from 20% to 28%) in the use of smokeless tobacco from 1985 to 1989.[3] Among NCAA baseball players an alarming 57 percent use. This increase is no accident but a direct result of a sophisticated marketing campaign that advertised and promoted the use of low nicotine oral snuff starter products as part of a graduation strategy that intended new users to graduate up to higher nicotine brands as dependence progressed. These brands are highly addictive and high in cancer causing agents called nitrosamines.

Since the last hearing I have conducted additional research on this matter including an analysis of nicotine bioavailability in oral snuff brands with the American Health Foundation and collected additional evidence on how the industry markets oral snuff starter products and US Tobacco Company (UST) statements that show UST does manipulate nicotine bioavailability.

1.) Manipulation of Nicotine Levels

Oral snuff manufacturers intentionally control the nicotine levels delivered to their consumers by controlling the amount of total nicotine in their brands, the level of free nicotine that is available for uptake into the body and in the case of Skoal Bandits which uses portion packs the size of the dose.

Free nicotine, refers to unprotonated nicotine which is rapidly absorbed across the membranes of the mouth into the body. Free nicotine is formed as the pH of the tobacco increases. At a neutral pH of 6.0 no nicotine is unprotonated at a pH of 8.0 about 70% is. [4]

Total nicotine is controlled through selection and blending of tobacco leaf. Free nicotine levels are controlled through fermentation and/or the addition of alkaline buffering agents such as sodium carbonate and ammonium carbonate. These two additives appear on the additive list that the industry trade association, the Smokeless Tobacco Council, supplied to the Subcommittee this in April. Mr. Taddeo, (president of US Tobacco), denied controlling nicotine in UST products at the April hearing of the Subcommittee. However, the Swedish Tobacco Company which also manufacturers oral snuff readily admits controlling nicotine bioavailability. The Company states in a 1994 Report, Smokeless Tobacco From Gothenburg on its production process,

> **"In order to release the nicotine from the tobacco, the snuff is made slightly alkaline-sodium carbonate is added during the production process as this alters into bicarbonate."**

The same company produces a fact sheet entitled "Snusets innehall". "The content of snuff". (see appendix B) According to paragraph two of the fact sheet:

"The additives added to all brands during the production process are:
-Salt which is used as a flavor since centuries.
-Sodium Carbonate (Na2CO3), which is active increasing the pH-level, which makes nicotine more easily released from the tobacco and subsequently facilitates the uptake of nicotine through the mucous membranes of the mouth. The sodium carbonate is altered in the snuff into bicarbonate (NaHCO3).
-Propylene glycol which is a moisturizer."

Section 4 provides a series of statements from UST that were read into the record of the 1986 Marsee Court case that show the industry's intent to control nicotine bioavailability.

2.) Starter Brands and the "Graduation" Strategy

If a new user starts with the standard high nicotine brands such as Skoal Fine Cut or Copenhagen, a toxic response such as dizziness or nausea may occur and new user is more likely to quit before tolerance to the toxic effects of nicotine develops. To respond to this problem and expand its user base UST developed a low nicotine starter brands: first Happy Days, in the late 1960's and then Skoal Bandits in 1983 and Skoal Long Cut in 1984. These brands were much more heavily advertised than Skoal Fine Cut or Copenhagen and the only ones free sampled. The Company also developed a graduation strategy that called for new users to "graduate" up to higher brands over time.

Of major concern with the high nicotine brands is that these brands are highly addictive, making it very difficult for consumers to quit event if they are suffering from health problems. Also, the higher nicotine brands have much higher levels of cancer causing nitrosamines. In June, the American Health Foundation was funded by the National Cancer Institute to assess nicotine and pH of commercial U.S. snuff brands and I participated in the study. The study found that the starter brand Skoal Bandits has a low dose of nicotine and low pH. For the other brands tested, percent of nicotine did not vary but the pH did, rising from 7.2 in Skoal Long Cut, to 7.5 in Skoal Fine Cut, to 8.0 for Copenhagen. By adjusting the pH, the amount of free nicotine rises sharply from the starter brands to the high dose Copenhagen, thus confirming UST's graduation strategy.

Free Nicotine and pH in Oral Snuff Brands

	Samples	pH	% Nicotine	% Unprotonated Nicotine
Copenhagen	6	8.0±	2.91± 0.18	57.4± 17.8
Skoal Fine Cut	6	7.46± 0.16	2.81± 034	29.1± 7.5
Skoal Long Cut (varying brands)	6	7.2	3.03	22.9
Skoal Bandits	6	5.37± 0.13	2.29± 0.46	.3± 0.2

Source. American Health Foundation 1984

The results are similar to what Dr. Henningfield of NIDA found in his 1994 study.

Section 4 of my testimony lists 16 statements made by representatives of UST. These statements include specific references to the marketing of starter brands, a graduation strategy or nicotine manipulation.

Three documents from the Marsee Court Case dealt with UST's Lotus Project on which the graduation strategy was based and I submitted these to the Subcommittee in March. The first is 1968 minutes from a meeting of UST in which UST vice president Mr. L.A. Bantle stated:

> **"We must sell the use of tobacco in the mouth and appeal to young people...hope to start a fad."** (see Appendix D-11)

In the memo Dr. Bennett of UST summarized the meeting's recommendations and points 5 and 9 called for:

> **"Conduct animal studies on the health aspects of snuff. This is to be a private investigation and strictly confidential." No.5**
> **"Develop new products. For example artificial snuff-a consumable confectionery which would satisfy the snuff user." No.6**

Two 1972 documents dealt with the"Lotus Project". In April, Mr. Taddeo told the Subcommittee:

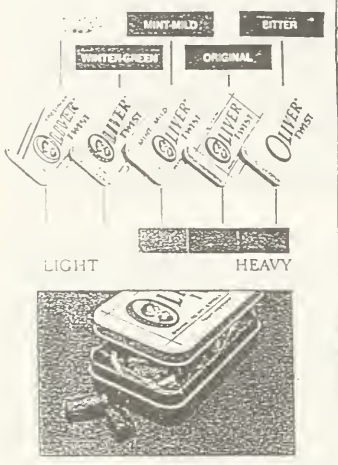
> **"The document (Lotus) relied upon by Dr. Connolly to support his assertion was written over 20 years ago, does not mention Skoal Bandits, was not created by US Tobacco and does not reflect US Tobacco policy."**

The Lotus Project was first developed by United Scandia International which was a joint venture between US Tobacco and Swedish Tobacco. The June 2, 1972 memo was on US Tobacco Company (UST) letterhead and described the activities of two working groups, one from UST and the other Swedish Tobacco. The second Lotus document, dated July 18, 1972, were the minutes of a meeting held at UST headquarters in which Mr. L.A. Bantle stated that he wanted a Lotus Project, smokeless tobacco in a portion pack for the U.S. market and instructed a UST task force to do so. As part of that memo, the Lotus Project was described and the target group was defined as **"new users, mainly cigarette smokers, age 15-35"**.(see Appendix D-23) The strength of the new product was termed **"nicotine satisfaction"** and the product was compared to UST's existing brand Happy Days. The documents were created by US Tobacco and described their Lotus Project which was the basis of their graduation strategy. UST introduced in a portion pack of oral snuff identical to the product described in the memo in 1983 called Skoal Bandits. Although, Mr. Taddeo of UST denies use of starter brands, another snuff manufacturer readily admits their use.

The Hermann Kruger tobacco company from Denmark sells smokeless tobacco in the US under the brand name Oliver Twist which comes in five strengths ranging from light to heavy. The lightest

brand is called "Freshman" and according to the company's instructions, "perfect for beginners". Bitter is the highest strength brand and is for "Senior connoisseurs and experienced smokers".

Brochure Oliver Twist



Manufacturer
HERMANN KRUGER's EFTF. A/S
Odense - Denmark

OLIVER TWIST is made in 5 distinct varieties.

Freshman:*	With a taste of anise light and fresh — perfect for beginners.
Wintergreen:	A refreshing taste of wintergreen — a perfect combination with the taste of supreme quality tobacco.
Mint-Mild:*	Fresh peppermint flavor that tempers the taste of tobacco. Preferred by women.
Original:	An old recipe based on sweet licorice and a genuine taste of dark fired tobacco. Excellent for experienced smokers and connoisseurs.
Bitter:*	Larger sized rolls with a seasoned flavor enhancing the taste of dark fired tobacco. For senior connoisseurs and experienced smokers.

A tin of **OLIVER TWIST** contains up to 40 portions.

* Available only in specialty smokeshops.

UST is not the only oral snuff manufacturer to employ low nicotine starter products. The Pinkerton Tobacco Company whose present company is the Swedish Tobacco Company manufactures a low nicotine product called Renegades that is sold in Skoal Bandits-like teabag pouches and a high nicotine brand called Red Man oral snuff. The Conwood Company sells a low nicotine brand, Hawken and high nicotine brand, Kodiak.

According to the American Health Foundation research the presence of unprotonated nicotine in Hawken was only .7%± 1.2 percent and Kodiak 68.3± 6.0 percent (6 samples).

3.1 Advertising and Promotion of Starter Brands

The only products free sampled by UST are low nicotine brands Skoal Bandits, and Mint and Cherry Skoal Long Cut. Cherry is a flavor which is particularly appealing to young people because of the sweet taste. Oral snuff manufacturers promote and advertise starter brands through free sampling which is done through the mail, at sponsored events and in UST's College Marketing Program.[5] During the last six months of 1984 over 400,000 samples were mailed in response to magazine ads.[6] According to the Federal Trade Commission,[7] 13% of all advertisers and promotional expenditures went for free sampling in 1991 and 20% for public entertainment which included sponsored rodeos, auto racing, music concerts and other events where free sampling is routinely done.

According to National Leading Advertisers (NLA), advertising expenditures for the low nicotine brands far outweigh those for the higher nicotine brands. In 1983, total US Tobacco advertising dollars for Skoal Bandits was 47% while the brand made up only 2% of market share by weight. Copenhagen, the highest nicotine brand, had only 1% of advertising expenditures but 50% of market share. UST spent $5.8 million in 1990-91 for print advertising for Skoal or Skoal Bandits. No advertising was reported for Copenhagen.[8]

Advertisements for the low nicotine brands further support their role in the graduation strategy. The ads provide non-users instructions how to use oral tobacco. A text for a Skoal Bandits brochure reads, **"It's as easy as 1-2-3...All you do is put it between your cheek and gum--the refreshing taste comes right through."** Another 1979 ad for Happy Days provides the potential consumer question and answer from former Dallas Cowboy, Walt Garrison.

> **"Q: Does "going smokeless take some getting used to?"**
> **"A: Sure. At first you could feel a slight irritation on the gum, and the tobacco may move around your mouth more than it should, and you might work up too much saliva. But learning is part of the fun and things pass with practice. Two weeks should make you a pro."**
> (Appendix E)

This ad actually instructs the new user to ignore a natural warning sign of disease, "irritation".
An ad for Happy Days quotes former baseball player Carlton Fisk, **"For you guys just starting out"**, when he described the low nicotine Happy Days.[9]

Two ads (Appendix G & H) show how advertising supports the graduation strategy. The first ad is Skoal Bandits and uses a selling message; "Introducing Skoal Bandits." A coupon for a free sample accompanied this ad. In Contrast, the ad for

Copenhagen had no free sample and only a simple selling message; "Sooner or Later It's Copenhagen." No coupon appeared with this ad.

A 1986 brochure for Skoal Bandits offers new users instructions how to use the product. According to the brochure:

> **"How long should I keep the pouch in my mouth? If you haven't tried Skoal Bandits before, we recommend that yo keep your first one in for about a minute-then remove. Like your first beer, Skoal Bandit can be a taste that takes time to acquire and get the most out of. After four or five Skoal Bandits you'll find you've developed quite a taste for them and you'll want to keep a pouch in as long as the flavor lasts. This varies from person to person."**
> (see Appendix H)

In combination, the UST ad campaign clearly shows the intent to promote experimentation with low nicotine starter products.

4.) UST Statements on Nicotine Manipulation, Use of Starter Brands and Graduation Strategy

At the April hearing, Mr. Taddeo stated:

> **"U.S. Tobacco does not in any way manipulate the nicotine levels in the smokeless tobacco products, nordoes it control the nicotine content of its tobacco products before, during or after the manufacturing process. Furthermore, U.S. Tobacco does not employ any marketing strategy based upon a theory that consumers can be enticed to begin using low-nicotine "starter" smokeless tobacco products, and subsequently caused to "graduate" to products with higher levels of nicotine."**

To correct the record, I am submitting 15 statements of UST that show the companies' intent to control nicotine bioavailability and employ starter products as part of a graduation strategy.

Statement 1.

"Flavorwise we <u>should</u> try for innovation, taste and strength, nicotine should be medium. Recognizing the fact that virtually all tobacco usage is based upon nicotine, 'the kick' satisfaction. Thus, the project can be defined as follows:"

by Per Erik Lindquist
U.S. Tobacco Sr. Vice President-Marketing
U.S. Tobacco -Intra-company correspondence
From: Per Erik Lindquist
To: Mr. B.J. Nova, President Tobacco Div.

Source: U.S. Tobacco document no.210 1124
Date: June 5, 1981
Marsee Court Transcript, pages 1661-1662
read into the record by Mr. Braly

Statement 2.

"<u>Progression theory</u> is conceptually valid but to make it work the <u>starter</u> brands should not be positioned as such. A number of men who find Copenhagen a shock to start are comfortable with Hawken et al brand, it is lower on the table but don't accept Happy Days because nobody wants to look like a beginner even if it's the first time,"

Source: U.S. Tobacco Co. Document 2473952,
Date: May 1,1982 Marsee Court Transcript page 111
vol.4, read into the record by Mr. Braly

Statement 3.

(Skoal Bandits) " will continue to fuel the new user base to assure <u>graduation</u> to our priority moist brands."

Source: U.S. Tobacco Co. Document no 2077832 Marsee Court Transcript page 112, vol.4, read into the record by Mr. Braly

Statement 4.

"The Graduation Theory "
"New users of smokeless tobacco--attracted to the category for a variety of reasons are most likely to begin with products that are milder tasting, more flavored and/or easiest to contain in the mouth. After a period of time there is a natural progression of product switching to brands that are full-bodied, have flavored more concentrated tobacco taste than the entry brand."

Source: U.S. Tobacco Document no. 2473950 Marsee Court Transcript pg. 112 vol 4 read into record by Mr. Braly.

Statement 5.

"This brand (Happy Days) has been clearly positioned as a starter product","increase the kick in the product."

Source: U.S.Tobacco Document no. 2143461 Marsee Court Transcript pg.114, vol 4, read into the record by Mr. Braly.

Statement 6.

"Product Graduation Process"

"The Smokeless Consumer Marketing Representative must be aware of the importance of developing new users on a continuing basis and the importance of developing basis and the graduation sampling brands and competitive brands."

Source: U.S. Tobacco Document no. 2215172 Marsee Court Transcript Pg. 114, vol 4, read into the record by Mr. Braly.

Statement 7.

"Sampling Skoal Bandits often and intensively in and around the retail account to create new customers and feed the graduation process".

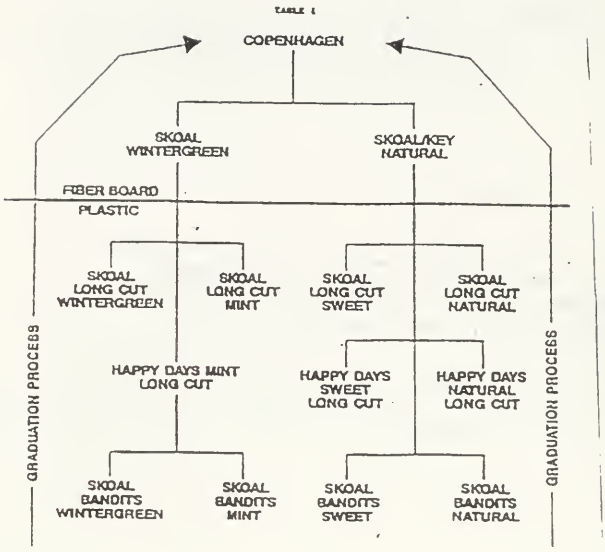
Source: U.S. Tobacco Document no. 2101576 Marsee Court Transcript Pg. 115, vol 4, read into the record by Mr. Braly.

Statement 8.

"Our sales and marketing groups have asked for a W.B. type chew with less strength saying the present product contains too much nicotine for the type chewer to whom they would like to direct the sale of such a product."

Source: U.S. Tobacco Document no. 4367088 Marsee Court Transcript Date: 8/30/76 Pg. 115, vol 4, read into the record by Mr. Braly.

Statement 9.



UST Document no. 12017104, vol. 5, page 12,13, Court Exhibit no 100.

Statement 10.

"Aside from appealing to smokers, the new product (Skoal Bandits) is designed to hook consumers into what Mr. Nova (President U.S. Tobacco) called a "graduation process" from Bandits to Skoal itself and then to Copenhagen, the company's strongest chewing tobacco."

Source: Feigelson, J. Ad Age East 3/18/83, p.486

Statement 11.

"As far as our strategy for entering a new market is concerned-for each market there is asset of criteria which have been established, and must be met. Skoal Bandits is the introductory product, and then we look towards establishing a normal graduation process."

Source: Jack A. Frick, Executive Vice President, U.S. Tobacco, Up to Snuff, US Tobacco Co., Spring 1985

Statement 12.

"Yet U.S. Tobacco routinely adds chemicals to its snuff to deliver the free nicotine faster and to make the product stronger."

Source: Larry Story, (former U.S. Tobacco chemist) Wall St.J. 10/26/94

Statement 13.

"The fermentation process involves adding chemicals and, at the end, you add some more chemicals which increase pH too."...."Without increasing the pH," he says, "you couldn't get nicotine release."

Source: James C. Taft (former U.S. Tobacco chemist) Wall St. J. 10/26/94

Statement 14.

"It (Copenhagen) was brought up to a pH of 7.8 by adding more sodium carbonate and ammonium carbonate."

Source: Larry Story (former U.S.Tobacco chemist) Wall St. J. 10/26/94

Statement 15.

"For people who haven't tasted (snuff) you'd of course begin them on a product that had a little tobacco taste, but wouldn't turn them off."...."The graduation is to a more tobacco-y product..to a stronger product(s)."

Source: Barry Nova
former president, U.S. Tobacco Co.
Wall St.J. 10/26/94

Statement 16

"Some people will remain with Bandits, and some people will get into a sort of graduation process. The bottom line, and we must never forget the bottom line, is that Bandits is a vehicle that is going to expand the use of smokeless tobacco."

Source: Manuel Leitao
Executive V.P. US Tobacco
Up to Snuff-Autumn 1984,pg 2

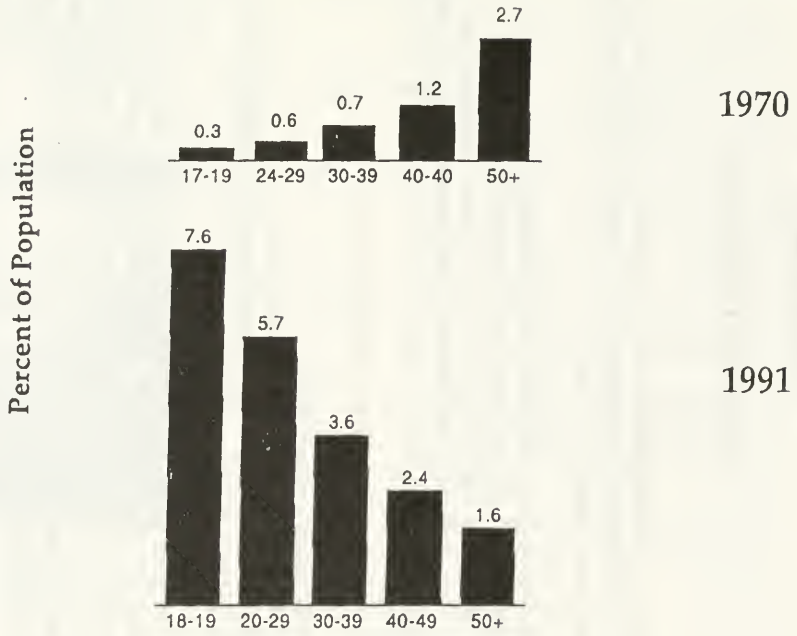
Conclusion

Based on this evidence there can be no doubt that UST manipulates nicotine bioavailability in their oral snuff brands and employs a graduation strategy based on free sampling of low nicotine brands with the intent of causing and maintaining nicotine among young males with no history of tobacco use. The marketing campaign has resulted in a surge in use among adolescent males.

Other nations that were recently faced with the introduction of oral snuff into markets banned the products including Australia, New Zealand, Hong Kong and the European Community[10].

The long term impact on oral health and oral cancer from this campaign will be devastating unless something is done immediately. Based on this evidence submitted to the Subcommittee, oral snuff should be classified as a drug by Food and Drug Administration.

Prevalence of Snuff Use Among Males 1970 and 1991



Source: 1991. National Health Interview Survey (NHIS)
1970: National Health Interview Survey (NHIS)

GOTHIA TOBAK
INGÅR I SVENSKA TOBAKS AB

APPENDIX B

SNUSETS INNEHÅLL

Snus tillverkas av **mald tobak** som fuktas med **vatten** (40–60 % beroende på märke). Övriga tillsatser är **godkända** av Livsmedelsverket **för användning i livsmedel** (snus klassas som livsmedel).

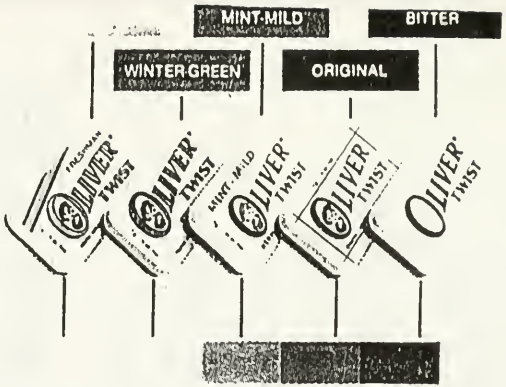
De tillsatser som görs i alla märken vid tillverkningen är:
–**Salt** som används som smakämne sedan hundratals år.
–Natriumkarbonat (Na_2CO_3), som är ett pH–höjande medel som gör att nikotinet lättare frigörs ur tobaken och därmed underlättar **nikotinupptagningen** via munslemhinnan. Natriumkarbonatet omvandlas i snuset till **bikarbonat** ($NaHCO_3$).
–**Propylenglykol** som är ett fuktbevarande medel.

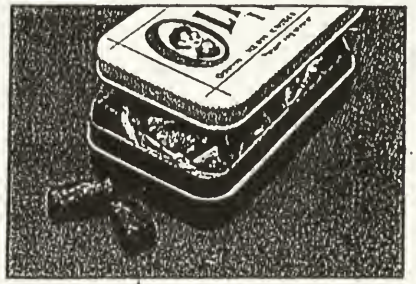
Dessutom tillsätts i vissa märken:
–**Glycerol** som är ett annat fuktbevarande medel.
–**Smakämnen** som t ex lakrits, citronolja, rosenolja, lavendelolja etc för att ge de olika märkena sin särprägel.

Snus innehåller naturligtvis också **nikotin** som kommer från den tobak man använder vid tillverkningen. Nikotininnehållet för de flesta snusmärken ligger mellan 0.8–1.0 % av snusvikten. Från detta avviker Light–varianterna som innehåller 0.5 % nikotin. Snusaren får dock inte i sig dock inte allt nikotin utan kroppen tar i genomsnitt endast upp 15–20 % av det teoretiska nikotininnehållet, men de individuella variationerna är stora.

Liksom all annan gröda, t ex grönsaker, innehåller även tobaksplantan vissa av de ämnen som kan förekomma i den jord som plantan växer i. Därför kan man med tillräckligt känsliga mätinstrument ibland mäta **spår av t ex bly, kadmium eller arsenik**. Större delen av den ingående mängden finns också kvar i snuset när det läggs ut.

Ibland påstås det att snus innehåller krossat **glas**, vilket givetvis är, och alltid har varit, felaktigt! Det som vissa konsumenter ibland uppfattar som glas i framför allt torrt snus är i stället saltkristaller.





Manufacturer
HERMANN KRÜGER's EFTF. A/S
Odense - Denmark

OLIVER TWIST is made in 5 distinct varieties.

Freshman:*	With a taste of anise light and fresh – perfect for beginners.
Wintergreen:	A refreshing taste of wintergreen – a perfect combination with the taste of supreme quality tobacco.
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Original:	An old recipe based on sweet licorice and a genuine taste of dark fired tobacco. Excellent for experienced smokers and connoisseurs.
Bitter:*	Larger sized rolls with a seasoned flavor enhancing the taste of dark fired tobacco. For senior connoisseurs and experienced smokers.

A tin of **OLIVER TWIST** contains up to 40 portions.

* Available only in specialty smokeshops.

IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF OKLAHOMA

BETTY ANN MARSEE,
Administratrix of the Estate
of MARVIN SEAN MARSEE,
Deceased,

Plaintiff,

vs.

UNITED STATES TOBACCO CO.,
a New Jersey corporation,

Defendant.

APPENDIX D

No. Civ-84-2777R

TRANSCRIPT OF JURY TRIAL PROCEEDINGS
Wednesday, May 21 1986

A p p e a r a n c e s:

HON. DAVID L. RUSSELL,
U.S. District Judge, Presiding

GEORGE W. BRALY, Esquire
DANIA DESCHAMPS-BRALY, Esquire
Braly & Braly
217 North Mississippi
Ada, Oklahoma 74820
Appeared for Plaintiff.

TIMOTHY M. FINNEGAN, Esquire
Jacob, Medinger & Finnegan
1270 Avenue of the Americas
Rockefeller Center
New York, N.Y. 10020
and
ANDY COATS, Esquire
Crowe & Dunlevy
1800 Mid-America Tower
Oklahoma City, OK 73102
Appeared for Defendant.

Volume 4

A P-2

use projects?

A. Uh-huh.

Q. Would you read the second full grammatical paragraph under that subject that begins with the word "flavorwise"?

A. "Flavorwise we should try for innovation, taste and strength, nicotine should be medium. Recognizing the fact that virtually all tobacco usage is based upon nicotine,'the kick', satisfaction. Thus, the project can be defined as follows:"

Q. All right. That's fine. Tell the jury what you mean by the words, and I quote, "the kick" that are included within quotation marks in the sentence that you just read?

A. All tobacco products contain nicotine. Nicotine gives the consumer satisfaction. Some would describe it as a pleasant feeling. Others would describe it as a kick. Others --

Q. And --

A. Others would describe it as a relaxing feeling.

Q. Do I understand from this statement that the U.S. Tobacco Company and yourself recognize that virtually all tobacco usage is based upon the kick from nicotine?

D-3

IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF OKLAHOMA

BETTY ANN MARSEE, Administratrix of the Estate of MARVIN SEAN MARSEE, Deceased,

Plaintiff,

vs.

UNITED STATES TOBACCO CO., a New Jersey corporation,

Defendant.

No. Civ-84-2777R

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Volume 5

D-4

an offer of proof with respect to the series of company documents. Company Document 4486792, dated October 5th, 1981, that the significance of this document will be to show, one, that the defendant knew that nicotine was the active physiological agent in tobacco, that that term that physiological agent had a code word that the company called "strength," that they knew how to manufacture snuff at levels, for instance, such as Happy Days that ranged from a nicotine level of .07 percent to Skoal with a nicotine level of 1.5 percent, that they, in fact, the numbers just given amounted to something that the tobacco company has called and does call in the company documents free nicotine as distinguished from total nicotine, that they manipulate the total nicotine to the free nicotine based upon adjustments and in what chemists call the pH of the snuff; that this document taken in conjunction with Document No. 1017101 and, in particular, the third page, fourth page, the third page of that document, which is 2017104, which is a table, which is labeled a "graduation process" and in conjunction with the Document No. 2286701, which refers to a sampling program for Happy Days, and that sampling -- that Happy Days is our primary sampling tool as well as

D-5

111

our starter product. That that refers back to the previous October 5th document, which shows Happy Days as having the lowest level of nicotine, that the graph shows Skoal in this instance and Happy Days right above it at the bottom of the graduation process, and with Copenhagen with the highest nicotine level at the top of the graduation process.

Further, the witness will testify that in Document No. 2473952, dated May 1, 1982, states the "progression theory is conceptially valid, but to make it work the starter brand should not be positioned as such. A number of men who find Copenhagen or Skoal too stout are comfortable with Hawken et al. brand, it is lower on the table, but don't accept Happy Days because nobody wants to look like a beginner even if it's the first time, coupled with statements on the preceding page, on the same memorandum that say, "The reason most men start dipping and chewing is because they are offered product from a friend or a contemporary. The influence of an older male relative is more cultural than direct. The importance of advertising cannot be minimized. Of course, few mean will admit to its persuasion.

THE COURT: Slow down.

D-6

112

MR. BRALY: "Of course few men will admit to its persuasion."

Document No. 2077832, stating that Skoal Bandits, which is at the bottom of the previous graduation chart, "will continue to fuel the new user base to assure graduation to our priority moist brands."

Document No. --

THE COURT: I'll tell you what. Why don't you bring the jury in and we will just send them off tonight.

MR. BRALY: Document No. 1023186-89, the objective according to this document is to introduce a product that will fill the gap between Bandits and Skoal in our graduation process and these words are underlined by the tobacco company.

Document No. 2473950, market research document prepared by the marketing consultants for U.S. Tobacco Company, the title of the document is "the graduation theory." It says in it in the first paragraph, "New users of smokeless tobacco -- attracted to the category for a variety of reasons -- are most likely to begin with products that are milder tasting, more flavored and/or easier to control in the mouth.

D-7

"After a period of time, there is a natural progression of product switching to brands that are more full-bodied, less flavored, have more concentrated 'tobacco taste' than the entry brand." The witness will testify that those are code words for "nicotine."

MR. FINNEGAN: May I have that marked with the documents, Mr. Braly.

(Handed to counsel).

MR. BRALY: There is one document that you have got, Judge. The document dated June 5th, 1981, Document No. 1037818-20. It is a document on U.S. Tobacco stationery from P. E. Lindqvist, senior vice-president of marketing, to Mr. B. J. Nova, Executive Vice-President and President of the Tobacco Division.

The second page of the document says, "Taste and strength (nicotine) should be medium, recognizing the fact that virtually all tobacco usage is based upon nicotine ("the kick") satisfaction.

(The following proceedings were had IN OPEN COURT.)

THE COURT: Ladies and gentlemen, you don't even need to be reseated. This is taking longer than we expected. So I think we will just go ahead and

Snuff and Chewing Tobacco
Research - Manufacturing - Marketing
Meeting

New York Hilton - January 22-23, 1968

Gentlemen:

The following minutes of the two day meeting have been compiled to record the interchange that transpired. The ideas and facts deal with the future of the Company's orally utilized tobacco products. This is not a word-for-word transcript but, rather, a compilation of the discussions which took place, representing a fair resume of the days' activities. It is sincerely hoped that you will find it to be an accurate and useful outline.

Respectfully submitted,

S. J. McConnell
Acting Secretary

In attendance:

Thomas W. Holley, Executive Vice President, New York Office
Stanley B. Erlandson, Vice President, New York Office
Milton Rothenberg, Vice President, New York Office
Louis P. Bantle, Vice President, New York Office
Charles A. Nickolaus, Jr., Chief Chemist, Chicago Factory
Ottomar D. Roeder, Branch Manager, Chicago Factory
William R. Quail, General Superintendent, Chicago Factory
Ward B. Bennett, Jr., Research Director, Nashville Factory
Hugh P. Midgett, Chief Chemist, Nashville Factory
James C. Taft, Research Chemist, Nashville Factory
Garland S. Teague, Jr., Research Chemist, Nashville Factory
Larry D. Story, Research Chemist, Nashville Factory
John M. De Voe, Manager of Industrial Engineering, Nashville Factory
John. W. Maury, Plant Manager, Nashville Factory
Jewel E. Byrum, Manager Leaf Department, Clarksville, Tennessee
Ward H. Matthews, President, J. C. Winter Co., Red Lion, Pennsylvania
Stephen J. McConnell, Public Relations, New York Office

(1)

PROCEEDINGS OF THE SNUFF AND CHEWING TOBACCO RESEARCH - MANUFACTURING - MARKETING MEETING

NEW YORK HILTON, JANUARY 22-23, 1968

Mr. Holley opened the meeting with a welcome to the group, and after proper introductions turned the meeting over to Dr. Bennett to act as chairman.

Since the meeting was to focus on the future, Dr. Bennett recommended several books which might be both interesting and valuable. The books, "The Year 2000," "Here Comes Tomorrow," and "New Concepts of Food Industry Marketing and Planning," outline various aspects of the future in the next third of a century and the year 2000. He noted that synthetics and computers will have a more prominent involvement in our lives. The use of nuclear forms of energy will replace conventional sources, and in less than 25 years the speed of travel will increase 2 or 3 fold. Dr. Bennett spoke of the future in space and the profound effect it will have on personal living and industry. Science may conquer almost all major diseases now known to man. When people consider these factors, they are forced to improve their creativity to meet future demands. As a Company, we must utilize our imagination and keep pace with the changes ahead.

Mr. Erlandson discussed the progress made in manufacturing products as a result of new machine innovation. He noted Skoal brand growth to 2 3/4 million, Happy Days' initial success, and that work on new flavors is being continued. Current processing has been mechanized. However, the curing process should be investigated. If this could be improved by

(2)

reducing the time required and the handling, significant economies would ultimately be realized. The establishment of the lab in Chicago in 1960 has been a successful step and will play a most significant part in the quality of current brands as well as the development of new products.

It was suggested that the group should focus on the following concepts:

1. To perhaps develop a more socially acceptable way of using moist brands, such as the "tea bag" concept.

2. To prolong the lasting quality through better packaging, such as the vacuum can. He noted that a "tennis ball" type container is now being used in Canadian markets. It will keep the product fresh for 18 months. The container is stamped with an expiration date.

The 18 month period may be too long and could be geared down to a lesser period of time. This type package might have far-reaching application in the export and military markets. It would enable us to alleviate many problems now faced in approaching distant markets, without having to look toward local manufacture.

Mr. Roeder said that a pack of this nature avoided rust problems and only added about 1kc per can to the cost. He also noted that fine-cut tobacco was about 33% of Chicago production today. In 1915 it was only 8%; 1920, 9%; 1940, 11%; and 1950, 17%. It would seem that these brands and this type product have the best growth potential. Mr. Roeder went on to mention that with lighter materials such as aluminum, weight and freight savings could be realized. However, due to the nature of our current packaging, he suggested that the amount of product contained

in a case be increased to obtain a unit with sufficient weight, thus avoiding transportation surcharges which might be forthcoming on small packages. Such tactical moves could save much revenue for the Company.

Mr. Rothenberg said that, aside from the usual adjustment and normal resistance to change, he felt that from a sales viewpoint it would not pose any major problems. He noted the success of the two day shipping schedule, but cautioned that we should not lose flexibility by computer-oriented methods of order processing and shipping procedures.

Mr. L. F. Bantle said that now is the most opportune time to convert people to using moist brands. We must sell the use of tobacco in the mouth and appeal to young people. This year our ads will be in line with the convenience of using snuff and/or chewing tobacco and we hope to start a fad. The theme will be "Tobacco Too Good to Smoke."

Mr. Midgett said that we should eliminate the fear of changing products and present moist brands in a better light. We should attempt to eliminate the stigma tied to the need to expectorate, and we should encourage proper use of the products.

Dr. Bennett noted that research technology is here, and what should be done is to ascertain the course to take and the new products desired.

Mr. L. F. Bantle said that perhaps the best route would be to leave current brands alone and develop entirely new brands. He added that basic consumer research by an outside agency might prove revealing. We might investigate what the consumer finds objectionable, and what changes he desires to make the product attractive to him. Equipped with this information, we would be in a better position to suggest new products.

(5)

Mr. De Voe said that while conducting our survey, we should look for common habits such as ways of dipping and try to incorporate them for users when new products and packs are developed.

Dr. Bennett said that perhaps we should be working on a swallowable chew: a confection with nicotine (artificial snuff). This would eliminate expectoration and laxative effect of swallowing tobacco. Perhaps we should consider other uses for snuff.

Mr. Rothenberg said that the current "mug promotion" was a good one and we should capture a greater share of the market.

The effort will be better than past promotions since the consumer will undoubtedly wish to acquire more than one mug and will buy more snuff to obtain a set.

Mr. L. F. Bantle said that we might consider the use of coupons as a continuing promotion. We could have a premium catalogue and involve all Company products.

Mr. Roeder said we might consider a sales promotion effort involving valuable prizes. The cost might be less in the long run and it might create and focus a great deal of attention on our products.

Mr. L. F. Bantle said that basic research should be explored first to ascertain product desirability and to give the consumer what he wants.

Mr. Nickolaus said that further investigation of the cure cycle will be done to find which factors contribute most significantly to the end product.

Dr. Bennett said that continuous curing could be achieved. He asked those present to think in terms of when this might be required and if the need existed.

Mr. Matthews then discussed chewing tobacco, including scrap. Scrap chewing has recently leveled off after a declining trend since the 1800's. He noted that we desire to attract new customers without drawing upon snuff users. He said that we have introduced our new foil package just in time and this should help sales considerably, since new packaging from competitors has been felt. He said that experiments should be conducted and new flavors tested. These flavors should be definite and pronounced. Mr. Matthews said that sweet chewing tobacco was a very high percentage of the market. "Happy Jim" is semi-sweet; the new "Mr.B" is sweet, and "Winters Clippings" is a non-sweet chewing tobacco.

The past year has been a difficult one for J. C. Winter. However, the knowledge gained via experiment and the ultimate results of adopting new packaging and new product should make 1968 a good year. The direction at this point is much clearer than a year ago.

Mr. Nickolaus mentioned that a Teaberry flavor has been developed, and perhaps this could be used in a J. C. Winter brand.

Mr. Rothenberg said that the sales force can achieve distribution and conspicuous exposure. The rest is up to consumers' acceptance of the product.

Mr. Matthews suggested investigating the control of product processing efficiencies, and economies might be achieved by updating these methods. Current proceedures to clean a product result in about a 50% weight loss.

Mr. L. F. Bantle said that no advertising budget as such has been allocated at this point. Future expenditures will be predicated on development and distribution.

Mr. Holley noted that there are very few national brands in scrap chewing tobacco. Most brands are local.

Dr. Bennett said that the next item to be considered is the procurement of leaf, which is the foundation of our tobacco business. He noted we should be aware that the obtaining of the type and quantity is vital. He called on Mr. Byrum to give us an idea of the future. Mr. Byrum distributed a most informative, three page report and explained the Company's position in relation to total tobacco available, by type and grade. While explaining the figures, which were a review of the last 10 years, Mr. Byrum gave a fairly clear picture, even to those not familiar with the operation of the Leaf department, of just how the current situation was and in what direction it was heading. He noted that the Government controls the acreage, based on total supply requirement. This program was established in 1940. The major problem today is labor, since industrialization has drawn young people away from the field. In past years production has kept up with demand, even though acreage has been reduced. Advancing agricultural technology has increased the yield per acre. However, Mr. Byrum felt that this advancement has reached the saturation point, since yield in the true sense is governed not only by amount but by quality. The growing of tobacco plants too close together, for example, will result in diminishing returns, due to the fact that quality and therefore, total yield will be reduced. He also noted that increases in price will help keep the growers in the industry. Currently, tobacco growing has become a less profitable business. He felt that the time

will come when we will have to contract with farmers directly to grow our tobacco for us. This being done now in Canada.

According to Mr. Byrum, the outlook in the near future for the availability of tobacco by type required by the Company is as follows:

1. Dark Fired - Adequate (we use a very high percentage of this type).
2. Burley - No Problem (we use a very small percentage of this type).
3. One Sucker - Adequate now (we use a small percentage of this type).
4. Green River - Doubtful (we use a high percentage of this type).

He also mentioned that Burley stem is very hard to get and we have purchased as much as we could and made as many arrangements as possible to acquire stocks in the future.

Dr. Bennett said that perhaps we should be thinking in terms of what can be done when we are unable to economically obtain the required tobacco stocks. For example, if we can not get the Burley stem, what can we use in its place? Should we become involved in agricultural research on tobacco we require, such as Dark Fired? Would our findings help the farmer, and help us then to fill our needs? Imported brands are not suitable at this point. Perhaps they will improve, and in time this may well be the source of supply to look toward.

Mr. Matthews said that the procurement situation in the Pennsylvania area was much the same. However, the main difference was the fact that much of their procurement is done after the tobacco has been aged and partly processed. Thus, weight losses are a lesser factor.

Mr. Midgett asked if economies could be realized by going to lower

grades of leaf. Mr. Byrum said that at this point it was not probable, due to the current supply and demand situation. He said that in the future we might be able to look in this direction, provided we could maintain consumer satisfaction and product acceptance.

Mr. Rothenberg expressed appreciation for the meeting, and noted that the interaction was most valuable. He said it behooved sales personnel to be cognizant of procurement and processing problems.

Mr. Roeder said that feedback from sales and marketing to the factory would also be beneficial.

Mr. Quail said that they are currently looking for reaction information on the aluminum lids now being used on military shipments. He asked if we should expand the use of these lids.

Mr. Holley said that at this point it would be better to restrict their use and that feedback would be available soon, since Mr. Watson is now on a trip to European bases, and Mr. Lissy would soon be covering the Far East.

Mr. Teague noted that we should pursue continuing studies of bacteriology related to snuff and be equipped with answers before the questions are asked of us.

Mr. Rothenberg said that new flavor research should continue, since, based on the success of Skoal and Happy Days, this seemed to be the course to follow. He said that the sales force would endeavor to supply the feedback required to help guide research people in the most beneficial direction.

(10)

Dr. Bennett gave the following recap of the topics discussed and introduced for consideration:

1. Work toward development of new and varied high flavored chewing tobacco and snuff.

2. Work toward improving shelf life of our products through research and new methods of packaging.

3. Continue studies of curing process with an eye toward mechanization.

4. Conduct studies to ascertain consumer needs and obtain guidelines for product research.

5. Conduct animal studies on the health aspect of snuff. This is to be a private investigation and strictly confidential.

6. Investigate automation.

7. Conduct agricultural research and educate growers on facts that would be mutually beneficial. Help influence tobacco-oriented legislation.

8. Investigate other uses for tobacco.

9. Develop new products. For example, artificial snuff - a consumable confectionery which would satisfy the snuff user.

10. Consumer-oriented packaging. The avoidance of the consumer education aspect. The development gradually as opposed to radically.

11. Establish communication procedure for considering new ideas with proper feedback to the donor, even if the idea is not currently feasible.

12. To call meetings of this nature periodically and build on the foundation now established.

UNITED STATES TOBACCO COMPANY
INTRA-COMPANY CORRESPONDENCE

TO: Mr. L. A. Bantle, President
FROM: W. W. Watson, President - United Scandia International

June 2, 1972

LOTUS

The moist snuff user and manufacturer has, for a long period of time, desired and searched for a method of placing moist snuff into a single unit or portion for convenience of use.

Market research and our consumer suggestion file shows strong support for such a packaging concept.

To satisfy this consumer want there are several forms moist could take, such as - capsule, tablet, candy coated chiclet, or tea bag concept (Lotus). All of these concepts should be explored. However, as of today, much work has gone into the Lotus project.

1. A prototype machine is available with initial success.
2. Market tests (Sweden) of the packaging idea show strong acceptance from the consumer.
3. Lotus satisfies all but one of the product needs (product taste) and there is a strong belief that with hard work on the part of STA and UST a satisfactory product will be produced.

Therefore, for the immediate future, we must concentrate all efforts on Lotus.

There are and will be many problems to be solved before Lotus can be marketed. How important is it that UST and STA be first in the market with an acceptable product? If not first, should we not at least be second. My personal vote is to be first with the best damn product possible and soon.

Vol 25 pg 2225 stay
pg 2232 2-12-74

Pl. Depo Exh 14
TRIAL Exh. 158

To narrow the problem down, may we talk about what is the product to be.

Results of meetings held with the project group in Sweden and one meeting with the group in UST plus several smaller meetings, conclude the following:

1. There should be three products of three different tastes and strengths of nicotine.

   a. High nicotine, strong tobacco flavor for consumer who presently uses tobacco in the mouth.
      Can this be accomplished by using present product of Copenhagen or Ettna?
      Can it be accomplished by larger portion than present sample?
      Can this be done by using stronger tobacco colors in packaging?

   b. Medium strength of nicotine.
      Can this be accomplished by using a Happy Days product?
      Can this be accomplished by using medium size package?
      Can we use spirits such as rum, cognac, bourbon; wines - sherry; coffee, tea, for this product?
      Will the color of the package be medium in strength?

   c. Low nicotine, sweet product.
      Can this be done by using present size Lotus?
      Is there a milder snuff moist available than we are presently using (sweet dry snuff)?
      Do we flavor this product with honey, chocolate or vanilla?

Above are three objectives as to guidelines for product development. They are the best offerings thus far. What has been done to develop these products? Is it possible to develop any of these suggestions?

Word Bennett was the first to suggest that the paper being used for the inside sack was not allowing sufficient flavor to pass through. He is working on other papers. What is his progress?

A machine could be ready for use in Chicago by the end of 1972. Do we want this machine?

What do we do while we are waiting for the machine? I suggest we work like hell on the product. With no other suggestions coming forth, I advise that we go with the above outline as to product.

However, may I offer that to gain the advantage of many talents in U.S.T. that a small group be appointed by you, Mr. Bantle, to bring together what may be thoughts of manufacturing, product research, and marketing to agree on the steps to be taken.

You, Mr. Bantle, would be head of the group or group committee could report to you directly. May I not appear too bold to suggest a Coordinator be appointed and if it should please you, I would be honored and happy to act in this capacity. The reason for the suggestion of myself is that it would bring to the group the progress and work already done by S.T.A. Secondly, U.S.I. is very interested in obtaining the right Lotus package for international marketing and soon.

To my sorrow, this report is not the full answer to the problem, but it is my belief that it is a big step forward.

Please, Mr. Bantle, should you need any further discussion on this matter, the writer is most anxious to be of service to you.

Walter

WWW:hlm

D-7

Minutes from a Meeting in
Greenwich 7-18-72 at
Mr. L. A. Bantle's Office

Subject: The Lotus Project

Present:

L. A. Bantle	S. B. Erlandson
O. D. Roeder	W. W. Watson
P. E. Lindqvist	T. B. O'Grady
J. W. Haury	W. J. Leinen
R. T. Gaddis	W. R. Quail

Mr. L. A. Bantle opened the meeting by explaining that "Lotus" is the code name for smokeless tobacco in a portion pack form. This project is being launched this fall in Sweden by Swedish Tobacco Company. It is an understanding between the Swedish Tobacco Company and United States Tobacco to keep one another informed and to cooperate on this project.

Mr. Bantle further declared that he wanted a Lotus product for the U.S. market as soon as possible and that this product should not be a Copenhagen or Skoal in the portion pack form, but an entirely new product aimed at new consumers, mainly cigarette smokers.

Asked what information research could contribute towards the possible acceptance of the Lotus idea by the consumer, Mr. O'Grady stated that

1. float
2. lipburn
3. size of pinch

were dominating factors in creating problems for new users to get accustomed to smokeless. The Lotus idea could to a great extent overcome these problems, thereby making it easier to open up a larger market.

Mr. Bantle explained that in agreement with Swedish Tobacco Company, United Scandia International is going to offer Lotus to the international market. The product USI will offer may be choosen from either of the two mother companies, whichever company USI thinks is making the right product for X market. This could mean that several products might have to be developed although the ideal situation would be if the U.S.-Lotus could be used worldwide.

To accomplish a sound an rapid development of the Lotus project, Mr. Bantle declared that he wanted to set up a special task force with the following participants:

U.S.I.
P. E. Lindqvist
W. W. Watson

United States Tobacco Co.

W. B. Bennett	W. J. Leinen
E. J. Boyd	C. A. Nickolaus
R. T. Gaddis	T. B. O'Grady (C
J. W. Haury	R. L. Rossi m

This task force should report directly to Mr. Bantle and always bear in mind the secrecy of the project.

Before the meeting was ended several technical aspects of the project were discussed (flavored paper, size of pinch and homogenized leaf). Mr. Bantle in summing up this discussion declared that all possibilities to make the right Lotus product for the new consumer must be explored with every effort put into the project.

Mr. Thomas B. O'Grady has been appointed Chairman of this task force committee.

The next meeting of the Lotus Committee will be the middle of August. Members will be given sufficient notice as to the place, time and date.

APPENDIX C

THE LOTUS PROJECT

AIM: To make it easier for a new user to use tobacco in the mouth.

TARGET GROUP: New users, mainly cigarette smokers, age group 15 - 35.

PRODUCT:

A. Strength

1. Nicotine satisfaction.

   Mild like Happy Days
   Instant but not shocking.

2. Feeling in the mouth.

   As little harshness as possible on the gum and in the throat.

B. Taste

A flavored taste like mint, cherry or rum; not too strong to give harshness but strong enough to cover any salty bitterness or other unpleasantness for a new user in having tobacco in the mouth.

PACK:

A. Size of Pinch

Small enough for a new user to manage. The present Lotus size is perhaps okay. This point has to be closely worked out, takes into consideration the desired effects mentioned under "Strength."

B. Paper

The paper is only there to keep the tobacco in place and to make chewing look cleaner. The paper should be felt as little as possible and should allow flavor and taste to do its job as if no paper was there.

HELPING HAND

APPENDIX E

Walt Garrison answers your questions about moist smokeless tobacco.

Q: Walt, just what is Moist Smokeless Tobacco?

A: It's just what it says. Tobacco you enjoy without lighting up and smoking.

Q: And, a pinch is all it takes? Is that right?

A: You bet. Just take a small pinch in your thumb and forefinger and put it between your cheek and gum. Leave it there. No need to chew. The tobacco slowly releases its great flavor giving you real satisfaction.

Q: Does "Going Smokeless" take some getting used to?

A: Sure. At first you could feel a slight irritation on the gum, and the tobacco may move around your mouth more than it should, and you might work up too much saliva. But learning is part of the fun and these things pass with practice. Two weeks should make you a "pro."

Q: Is there a difference among the three brands?

A: There sure is. **Happy Days** is a mild satisfying blend of mint flavored tobacco while **Skoal** is full-bodied with the added good taste of wintergreen. **Copenhagen** is a stronger natural blend of choice tobaccos. All three are packed in convenient cans and every one is dated for freshness.

Q: What's the cost?

A: We figure an average user "dips" about 12 cans per week at a cost of about $1.60. Nice to know in these times when everything else costs so much.

Q: How do my people use Happy Days, Skoal and Copenhagen?

A: A lot more than you might think. Last year we sold over $25 million cans. No wonder all colleges from every part of the country are turning up all the time. Everyone of our chewers are musicians with their hands for extra flavor.)

Q: That's a lot. Well. Where can I buy Happy Days, Skoal and Copenhagen?

A: Just ask for it at your favorite tobacco counter. Or mail the coupon below and we'll send you a free can of Happy Days to get you started.

SEND ME MY FREE CAN OF HAPPY DAYS.

Print and mail to: "Smokeless Tobacco," 100 W. Putnam Ave., Ul Pl, PA 001, Greenwich, Conn. 06830

Name

Address

City

State

Zip

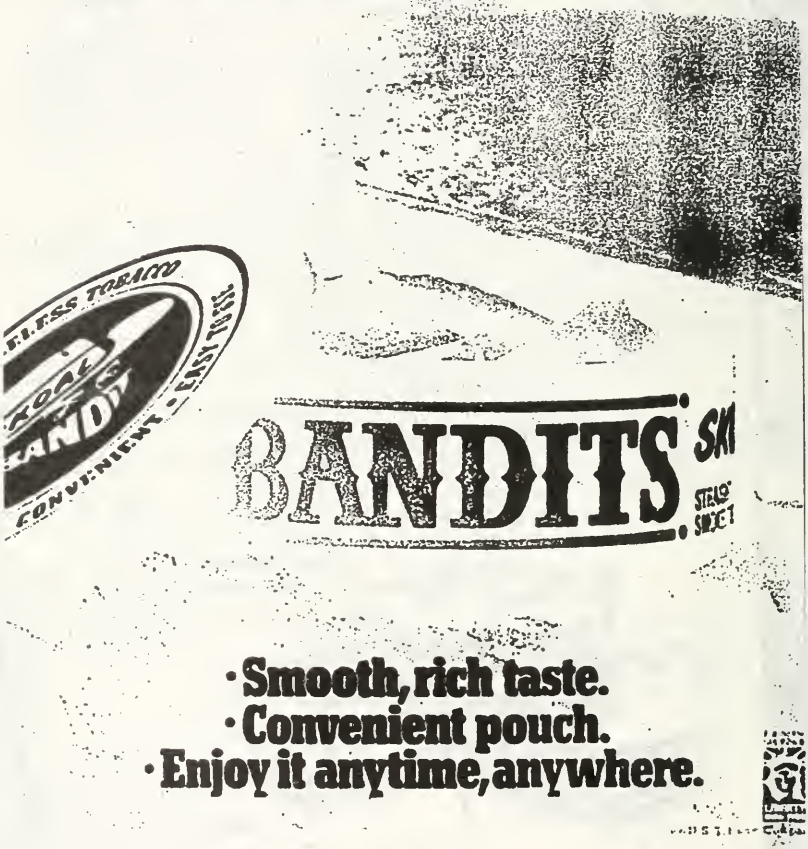
A pinch is all it takes!

1979

APPENDIX F

Introducing Skoal Bandits Straight

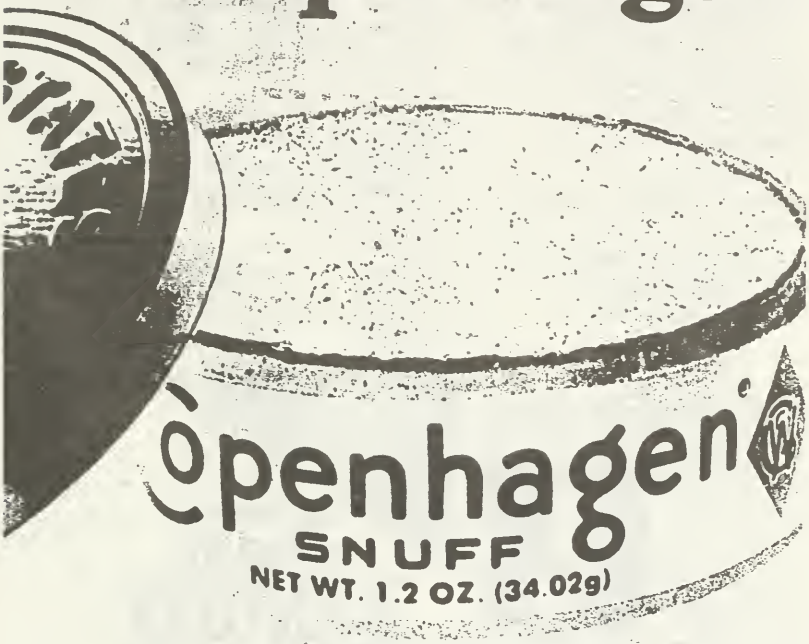
Smokeless tobacco has never been easier to enjoy.



- Smooth, rich taste.
- Convenient pouch.
- Enjoy it anytime, anywhere.

APPENDIX G

Sooner or later– it's Copenhagen.



There are a lot of smokeless tobaccos out there, but for a lot of guys there's only one. Copenhagen. For one good reason.

It satisfies.

Show your colors! Send for our color catalog packed with the newest caps, jackets, shirts and more. Send your name and address along with $1.00 (which may be applied toward initial purchase) to: Copenhagen P.O. Box 729, Sparta, NC 28675

Enjoy real tobacco satisfaction anywhere, anytime

New Skoal Bandits is tobacco with a difference: you can now get real tobacco pleasure without lighting up! Skoal Bandits are individual portions of fine quality tobacco with a subtle flavour of mint, packed in a handy pre-moistened pouch.

How do I use Skoal Bandits?

Simply take a pouch and place it between your upper lip and gum. Leave it there, but DON'T CHEW IT. The pouch works like a teabag, holding the tobacco in, but letting the flavour out. Because you don't light up, theres no smoke, so you can enjoy the satisfaction of quality tobacco anywhere, anytime particularly when smoking is inconvenient or prohibited.

How long should I keep the pouch in my mouth?

If you havent tried Skoal Bandits before, we recommend that you keep your first one in for about a minute – then remove. The next time you try another one, leave it in for a bit longer. Like your first beer, Skoal Bandits can be a taste that takes time to acquire and get the most out of.

After four or five Skoal Bandits you'll find you've developed quite a taste for them and you'll want to keep a pouch in as long as the flavour lasts – this varies from person to person.

Will Skoal Bandits give me the same satisfaction as other tobacco products?

Not the same, but DIFFERENT. Skoal Bandits are a new way to enjoy tobacco, they offer a unique kind of satisfaction. It's not the same as other tobacco products but you'll quickly acquire the taste and then really ENJOY THE REAL SATISFACTION OF SKOAL BANDITS.

Can I consume liquids with a Skoal Bandit in my mouth?

This is a personal preference, but many people do enjoy a Skoal Bandit while consuming liquids and find that neither flavour is impaired.

How much do Skoal Bandits cost?

A handy plastic can containing 20 pouches sells for around £1.10.

FREE T-SHIRT OFFER

For every three Skoal Bandits can inserts you collect, we will give you one of these exciting Skoal Bandits T shirts absolutely free.

To claim yours just fill in this coupon specifying which size or sizes you require and send them with your can inserts plus 50p P&P and handling, for each T-shirt to: David Brown Promotions Ltd., The Clock House, High St., Cranleigh, Sy. GV6 8RB.

I enclose ☐ Skoal Bandits can inserts plus ☐ P&P

Please send me ☐ T shirts

Size ☐ Medium ☐ Large ☐ XL

Please indicate number of T-shirts and sizes required in appropriate boxes

Name _____

Address _____

_____

I declare that I am a smoker aged 18 years or over

Signed _____

Please make cheques or PO's payable to: David Brown Promotions Ltd. Allow 28 days for delivery. Final date for receipt of applications: 30 Nov. 1985. Send applications to: David Brown Promotions Ltd., The Clock House, High St., Cranleigh, Sy. GV6 8RB.

Introducing

SKOAL®

BANDITS®

The new way to enjoy tobacco.

TOBACCO SATISFACTION
WITHOUT LIGHTING UP.

Advertising Age, August 8, 1983

Ad Age/East

...accounts

...bridge, Mass., to ...ell, Watertown, for ...nd pr. Previous... ...& Chivers ...both Amer... ...Division and

... Oil City, Pa., to ... Pittsburgh, from ... Harrisburg Savings Bank to ...states West Hart... ...Milford ...Philadelphia, an ...complex ...in 1981, to Decny ...advertising, its first ...Also to the ...Manufactur... ...agency of ...each account is ...

...elopment Corp., ...condominium ...River Associates ...condominiums in ...Harbor Project ...neighborhood revi... ...and Cam... ...to Pace Adver...

...sing & Public Relations, first agency of record for all...
Bristol Medical Electronic, Mansfield, Mass., to Slauch Vesmille Advertising, first agency. Also to the agency: Seela Entreprises, Fall River..., marketer of ...
Financial Federal Savings & Loan Assn., Miami, to Hargrove Associates, Cambridge, Mass., from Sandy Tinsley Advertising Miami, for an estimated $500,000 print, radio, tv and collateral material campaign.
New Jersey Safe Deposit Co., Fort Lee, N.J., to Keyes, Martin, Springfield, N.J., from ... New York.
NutriSystems Boston, a weight-control center with 13 Massachusetts ... to Provandie & Chirurg, first agency of record. Also to P&C: Foster-Miller, Waltham, Mass., a ... engineering company, from ... Kinney Inc., Natick; and National Service Cleaning, ... an asbestos removal company, first agency of record.

...s Suncoast to ...d coupon offer

...—The Pinellas ...t Development ...again use a free ...entice tourists to ...nd winter ...n book contains ...ts available for ...hops, night spots, ...activities and ...ns, according to ...count supervisor, ...vertising, Tampa, ...ne)! ...book also will in... ...in hotels, motels

...ll Seward ...ign to help ...l season ...upons were good ...y, the previous

...close to $1 mil... ...lti-media cam-paign," Mr. Ettes said, "hitting markets east of the Mississippi River domestically, along with the Canadian markets of Ontario and Quebec and the United Kingdom and Ireland."

Magazine ads and a direct-mail campaign aimed at the travel trade broke in mid-July. The consumer effort broke last week and will include magazine and newspaper ads, radio spots and direct mail.

Ads aimed at Great Britain will point out more accessible travel via added flights from PeopleExpress, Arrow Airways and Pan Am.

The tourism bureau expects to distribute 100,000 coupon books this fall, up from last year's tally of 85,000.

The resort communities include Clearwater Beach, Dunedin, Holiday Isles, Madeira Beach, St. Petersburg Beach, St. Petersburg, Tarpon Springs and Treasure Island.

'New York Times' ties in to marathon

New York—The *New York Times* will distribute this year's official spectator's guide to the Oct. 23 New York City Marathon in its Sunday, Oct. 16 edition.

To further promote the five-borough race, the T... [illegible]

Skoal Bandits blitz kicks off N.Y. entry

By JEREMY FEIGELSON

Skoal Bandits, the U.S. Tobacco Co.'s new attempt to lure smokers into the world of smokeless tobacco, has received a lively $150,000 introduction to the New York market. U.S. Tobacco spent that amount on a one-day "blitz" that included a luncheon at the Plaza Hotel after a "convoy" of Skoal racing cars stormed across the George Washington Bridge during rush hour.

Ex-Dallas Cowboy Walt Garrison, longtime Skoal ad spokesman, summed up much of the product's appeal as he addressed the luncheon with a Bandit in his mouth. "You don't have to expectorate, no matter how much you talk," he said, before talking a good deal.

The Bandit, a small pouch of wintergreen-flavored Skoal tobacco, is placed between the user's upper lip and gum, enabling its flavor to seep out while the tobacco itself remains in its tidy pouch. Company press releases describe Bandits as working on "the teabag principle," although teabags have never become popular as a convenience product for direct use in the mouth.

"The convenience, the cleanliness, in a product group that has been called unclean, give us an advantage no other company has," said Barry Nova, president of U.S. Tobacco's tobacco division.

A new tv spot created by Warwick Advertising, New York, appeals directly to smokers who want to cut down. The spot shows a 30-ish, urbane, *Esquire*-type model in a tweed sport jacket demonstrating how to use the product, and winds up by telling viewers: "You get great tobacco taste—without lighting up."

The product will be in national distribution this September, backed by $5 million to $6 million in advertising. The tag line for the campaign is "Take a pouch instead of a puff." U.S. Tobacco said it is investing $2 million in its New York area promotional campaign (AA, June 27).

"The positioning is pretty direct," said Mr. Nova. "I believe the cigaret companies are looking at us with a bit of anger. They're bound to get a little excited when you come out with a campaign like this."

The New York introduction and the new tv spot are important parts of an effort to establish Bandits as more than a rural and suburban product. Previous distribution of Bandits has been chiefly in the South, and most previous Skoal commercials have stressed a more rough-hewn appeal, featuring spokesmen like Mr. Garrison and singer Charlie Daniels.

Aside from appealing to smokers, the new product is designed to hook consumers into what Mr. Nova called a "graduation process" from Bandits to Skoal itself and then to Copenhagen, the company's strongest chewing tobacco. The success of those two products has given U.S. Tobacco a 40% increase in volume sales over the last five years. Because the product is aimed at new users of oral tobacco, Mr. Nova denied that Bandits will cannibalize the older brands.

The New York promotional effort is in many ways a model for Skoal's national promotional plans. It includes the tv spots, heavy radio and newspaper advertising throughout the metro area, a Skoal Bandits tote bag night at Yankee Stadium and the awarding of "Bandit of the Month" prizes to athletes on local pro teams who steal bases, intercept passes, make game-saving plays and so on.

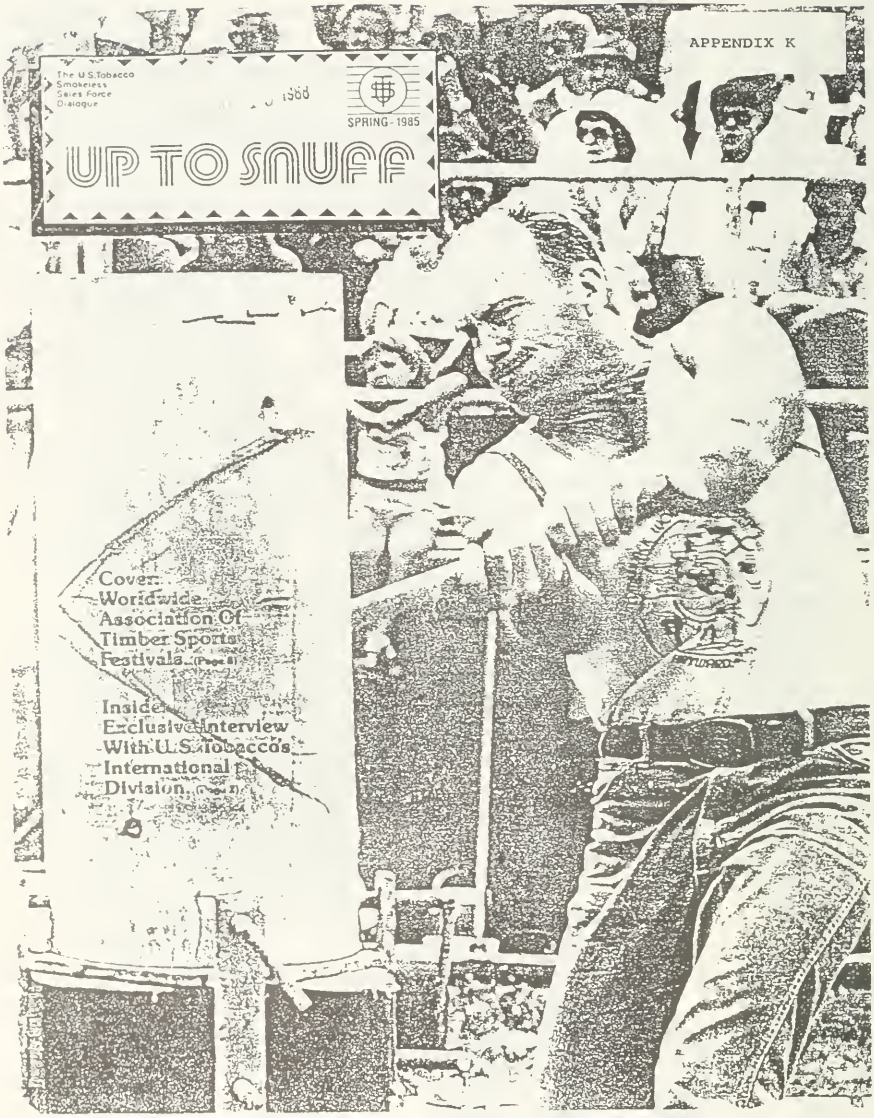
A "Catch a Bandit" street promotion, with free samples, t-shirts and various other promotional products given out to passersby, is also part of the campaign.

BBB to publish ad challenges

New York—The Better Business Bureau of Metropolitan New York has instituted a monthly case report that summarizes challenges to local advertising claims. To maximize effectiveness, the bureau will focus its advertising review effort on specific industries each month.

In June, it monitored travel industry ads and found that the ads' most common problem is the tendency to feature the lowest air fare price in big type without disclosing the highest price.

The bureau cited ads by Delta Airlines, Norwegian American Cruises, Tak-A-Charter Ltd., Freddie Laker, Olympus Tours and Pan American World Airways as concerned with that problem.


APPENDIX K
The U.S.Tobacco Smokeless Sales Force Dialogue
SPRING-1985
UP TO SNUFF
Cover:
Worldwide
Association Of
Timber Sports
Festivals
Inside:
Exclusive Interview
With U.S.Tobacco's
International
Division

market place. As far as actual introduction, we apply a number of different strategies to accomplish this task - whether it be with our own sales force or with a partner on a joint venture type arrangement or with the major distribution facility

U.T.S.
Mr. Africk, you mention strategies when talking about the international marketplace. What are our international strategies and, more importantly, how and why are these strategies different from the strategies we apply in this country?

Mr. Africk
First and foremost is the product, its positioning, and the communication of its basic benefits to the target user. In many instances we use our racing program as a promotional umbrella to create awareness. In 1985 we are sponsoring a very competitive Formula 1 racing team. Formula 1 races obtain over 1 billion television impressions per year. Broadcast live in most countries of the world, except the U.S.; the Formula 1 is an extremely effective way to establish awareness for Skoal Bandits.

As far as our strategy for entering a new market is concerned - for each market there is a set of criteria which have been established, and must be met. Skoal Bandits is the introductory product, and then we look towards establishing a normal graduation process. As was mentioned earlier, we have found through research and experience that flavor differences are substantial in different areas of the world. Even the use of certain words have different connotations when they are translated into different languages. So it really requires some great expertise. Our people are involved, not only in selling, they are involved in marketing, advertising, manufacturing, and distribution. Each one of our regional directors and area managers are totally conversant in all facets of the business.

U.T.S.
So basically what we attempt to do, is to integrate ourselves, our product, and our message, into the very culture of the country where we are introducing our products.

Mr. Ghiloni
That's of extreme importance when you start an international business. Trying to understand the marketplace and the needs of the consumer in that marketplace. And that extends from the logistics of distributing a product in an individual market, all the way to the specific taste preferences of that market.

U.T.S.
In your opinion, Mr. Africk, what would you say has been the easiest geographical location we have sought to penetrate?

Mr. Africk
First of all, entering a foreign market with an unknown product and product concept is never easy; but it is challenging and very complicated. The simplest entry is when we are dealing with a free market, such as that which exists in the United Kingdom. When we are dealing with the free market, we're able to do whatever we have to do without governmental and tobacco monopoly restrictions. This is not to say the free market is the easiest in terms of gaining consumers but rather the easiest in terms of doing what we have to do in order to get the job done. It becomes far more complicated when we are dealing with state owned monopolies which allow us to do certain things and restrict us from doing other things. This has been particularly true in countries such as Italy and France. In these countries, as a result of local laws and restrictions in dealing with tobacco monopolies and government owned tobacco monopolies, we have had to be very creative in terms of developing new methodologies for obtaining consumer acceptance of our products.

Mr. Lindqvist
U. S. Tobacco is investing quite a lot of money in order to speed up the awareness and education process. In order to do this, we have to rely quite a bit on television and print advertising during the initial launch to spread the know-how about the concept as much as possible. From there on, we try to zero in with more personalized marketing efforts such as one-on-one sampling. Interestingly enough, from our experience so far, one-on-one sampling appears to be as important a tool for building international smokeless sales as it has been for building domestic smokeless sales.

Mr. Ghiloni
In a nut shell, even though there's a product involved, what we're really doing is selling a concept a totally new concept.

U.T.S.
Quite a formidable task.

Mr. Fuller
That's correct. When we went into China, the opening comment was we don't have any need or use for this product. In their minds, there was no market for it because they did not know the product. It took considerable work and creativity to get the monopoly thinking along the idea that this was an effective new way to use tobacco.

Mr. Africk
What everybody really needs to understand is that we're not selling a candy bar or a package of gum. People are not lined up with knowledge of usage and gratification when it comes to oral tobacco. Everyone here has referred to it; our biggest job is an educational one. There is more and more concern regarding the use of combustible tobacco, there are more and more limits being placed on the use of combustible tobacco - therefore our timing is absolutely perfect in introducing what we call a "New way to enjoy tobacco".

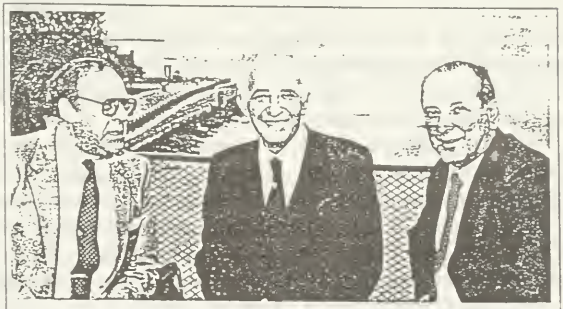
After the education process is completed, we find that the concept is very acceptable. Our consumer research indicates that there is a tremendous willingness on the part of potential consumers all over the world to try some new way to enjoy tobacco. So we are very fortunate to have all the years of experience that U.S.T. has had in developing markets here in the U.S., and to utilize that experience in developing world markets.

U.T.S.
One final question. Where do you see the international division in five years? How do you see it growing, and how do you see the market expanding?

Mr. Africk
We see the international area of our smokeless business playing a more important role each year in the total volume of this company. But how large and how high is up - I don't think anybody can give you an accurate answer. We are very optimistic about the future. We are about to complete arrangements for a manufacturing facility in Scotland which will service the entire Common Market. There are many justifications for this facility, including monetary, import duties and product freshenss.

There is little question that we will be manufacturing in the People's Republic of China, Australia, Sweden and many other countries in the future.

It is important to remember, though, that the volume will come gradually. I think you can safely say that in the future, we will have the nucleus of a hard-core user base and a profitable business! ★



L - R. Jack Africk, Natale Arena - President of the Italian Monopoly, and Leo Ghiloni pose during the sight seeing trip to New York City.

Mr. WAXMAN. Thank you very much, Dr. Connolly.

I want to thank the three of you for your testimony. I have some questions about all of this that I want to pursue with you. Of course I would like to pursue it as well with Mr. Taddeo, who's the chief executive officer of the United States Tobacco Company, but he refused to be here today. But when he did come before our committee many months ago, he gave a statement to us and that statement is as follows, and I am quoting from him: "U.S. Tobacco does not in any way manipulate or spike the nicotine levels in its tobacco products. Nor does U.S. Tobacco take any action to control the nicotine content of its tobacco products before, during or after the manufacturing process."

I am having trouble reconciling this statement with the testimony you've given us today. Now it appears to me what you told us is that there is nicotine manipulation. We started these tobacco oversight hearings last March. It seems like a long time ago. And what we heard about last March was spiking with nicotine. What you are telling us is it isn't a spiking of nicotine, it is the addition of chemicals that increase the amount of nicotine that the user can absorb.

Dr. Henningfield, that is your expertise. You have been working in this area. Is that what is going on? Are people exposed to different levels of nicotine not from what is in the product but because of the pH levels or additional chemicals that are added?

Mr. HENNINGFIELD. The dosing capacity of the products appears to be primarily controlled by pH level.

Mr. WAXMAN. And is the pH level something incidental to the product or is that determined by some other chemical additives?

Mr. HENNINGFIELD. Naturally occurring tobacco, to my knowledge, does not occur, at least in these kinds of tobaccos, at the high pH levels that we observed. Normal fermentation processes typically result in acidification, as anyone has found when they saw their wine turn to vinegar. But here we see very high pH levels in some of the products. That can be produced by adding a variety of chemicals, by complicated manufacturing processes. I'm not aware of the specific methods used.

Mr. WAXMAN. Well, I understand that there are some chemicals that have been used, sodium carbonate and ammonium carbonate. Would those affect the pH levels of these tobacco products?

Mr. HENNINGFIELD. Those are the kind of chemicals that would raise the pH. They are the kind of chemicals that are used in medications like nicotine gum sodium carbonate to raise the pH.

Mr. WAXMAN. So if they raise the pH level, that means that nicotine is released into the body and absorbed more than otherwise would be the case?

Mr. HENNINGFIELD. Yes. PH is the gatekeeper of nicotine release. PH is the gatekeeper. So the higher the pH level, the more the door is opened. And the only way you can get nicotine from the inside of the mouth to the bloodstream is by opening up a pipeline. PH is the gatekeeper that opens up the pipeline.

Mr. WAXMAN. And, Doctor Connolly, it is your testimony that the company can open up that pipeline in varying degrees in their products. In the starter product a lower dose of nicotine would be

released, and in the more graduated, so to speak, product, there would be a greater release of nicotine. Is that right?

Mr. CONNOLLY. Yes. Think about the old adage, your grandfather took you behind the barn and gave you a big hunk of chewing tobacco or some snuff. If you did that, generally the new user would throw up and wouldn't go on to use it, so you'd lose your consumer. UST, U.S. Tobacco, took cognizant of that and developed starter brands with very low nicotine bioavailability. Nicotine may have been similar to the other brands, but the pH was lower, so you wouldn't develop nausea, dizziness, upon first experimentation. So the user could gradually develop an immunity to the toxic response of the nicotine. But then when they did so, they would bounce up to the higher brands to get the kick from the higher brands of nicotine.

So it's good chemistry. If you wanted to expand your user base and you knew your current products caused people to get sick, whether it be Wheaties or whatever, you'd come out with a low nicotine brand, as U.S. Tobacco Company has done.

I would point out also, other tobacco manufacturers, all tobacco manufacturers, Pinkerton has renegade, low nicotine brands: High Country, they have a high brand, as well as Conwood. Conwood has their Hawkin brand, as well as a high nicotine brand, Kodiak.

Mr. WAXMAN. We asked U.S. Tobacco to give us information on the relative pH levels for each of its brands and the company refused to provide this data.

Dr. Henningfield, if they did provide this data, would we then know whether they, in fact, are manipulating the amount of nicotine the users would get?

Mr. HENNINGFIELD. You would at least know the different dosing capabilities of the different products. And again, if you just have nicotine content, that just doesn't give you the information you need to know the dosing capability over time. Nicotine content is just one part of the equation.

Mr. WAXMAN. Now, in the Wall Street Journal article, they had a chemist quoted as saying the company routinely adds chemicals to its snuff to deliver the free nicotine faster and to make the product stronger. I suppose that chemist was one of the two people that submitted affidavits to us today, and these affidavits, which I have read over, don't deny that they add anything to the product, they just say they do it for taste and not for manipulating nicotine. That, of course, was the testimony we got from the other tobacco cigarette manufacturers who said, yes, they can change the nicotine levels in the product but it is not for anything other than taste. And, Dr. Connolly, you are suggesting it is more than just for taste because they have a graduation strategy. On what basis do you say that they have a graduation strategy?

Mr. CONNOLLY. Well, with the documents submitted in the Marsee court case, those that are entered——

Mr. WAXMAN. Could we have that chart put back up, the chart from the Marsee case?

Mr. CONNOLLY. I think it's maybe a bigger chart. It's the graduation chart, it was chart number two. Yeah, this was Exhibit 100 in the Marsee court case. And what it described is what's called a graduation process. At the bottom of the process—I think Dr

Kessler presented this to the committee earlier. This is United States Tobacco Company document. It was Plaintiff's exhibit, but it was the industry's document that was entered into the case in Marsee.

Now, Mr. Taddeo at the last hearing said they—implied that the judge considered this evidence and ruled against the Plaintiff. But the fact was that Sean Marsee, the Plaintiff, didn't start with the Bandit. So the graduation process didn't apply.

But on this chart again, you have the lower nicotine brands, the Skoal Bandits, at the bottom of the chart. Next moving to Happy Days, which was a brand introduced in the late 1960's, early 1970's. Then finally, in 1984, they brought out the Skoal Long Cut; more recently the Skoal Long Cut Cherry. That Long Cut may also play an important role because the cut of the tobacco is wider, allowing a slower release and a more constant dose. Plus it binds well. It's sort of like Merrell Dow introducing nicotine into Oral Patch. And then finally you have your Skoal Wintergreen, finally up to Copenhagen.

So the evidence that I presented to the committee earlier this year was based solely upon United States Tobacco Company documents. And they clearly show a graduation strategy, they clearly show an intent to manipulate nicotine dose through the use of starter brands to cause and maintain dependence among consumers.

Mr. WAXMAN. Now, one of the strategies that they appeared to use to get people to start using their product is to give out free samples. Would they give samples of Copenhagen, which is described as the product that produces the greatest ingestion of nicotine, or would they give out samples of some other product?

Mr. CONNOLLY. Giving out samples of Copenhagen in the United States is probably like giving out samples of Russian cigarettes on the streets of Manhattan. It would kill any attempt to create a new marketplace. They don't sample Copenhagen, they don't sample Fine Cut. The brands that are sampled today now are your Skoal, Long Cut variety, in flavors such as mint and cherry.

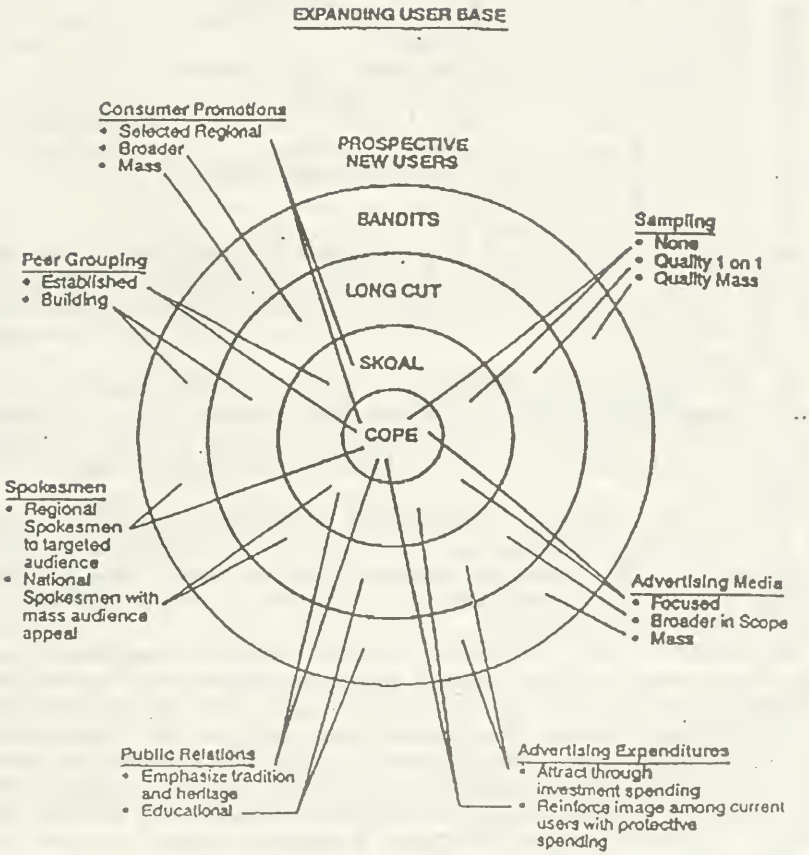
This is a package that's now sent through the mail and it's the only tobacco company that routinely sells products through the mail. I don't know how anybody can control youth access through the mail with tickets and samples. So they had a college marketing program on tour in the college campuses based on sampling. Again, it was the low nicotine brands.

Mr. WAXMAN. I just draw your attention to Subcommittee Exhibit 5A. It is a chart that has Bandits and Long Cut, Skoal, and then Cope in the center. And I presume Cope stands for Copenhagen brand. Would that reflect the graduation strategy?

Mr. CONNOLLY. I am not familiar with that colored chart, but there was one similar to that, I think at the Marsee court case, that said Bull's-eye. But if you look at it, I mean it speaks for itself. Prospective new users, sampling, I am looking at the Bandits, it says quality mass, which means, I think, to everyone. And the middle, none. That, to me, is a pretty revealing document. Advertising, mass advertising, focused for the Cope. And then public relations. That's quite a chart.

[The chart referred to follows:]

EXHIBIT 5A


EXPANDING USER BASE
Consumer Promotions
• Selected Regional
• Broader
• Mass
PROSPECTIVE NEW USERS
BANDITS
LONG CUT
SKOAL
COPE
Sampling
• None
• Quality 1 on 1
• Quality Mass
Peer Grouping
• Established
• Building
Spokesmen
• Regional Spokesmen to targeted audience
• National Spokesmen with mass audience appeal
Advertising Media
• Focused
• Broader in Scope
• Mass
Public Relations
• Emphasize tradition and heritage
• Educational
Advertising Expenditures
• Attract through investment spending
• Reinforce image among current users with protective spending

Mr. WAXMAN. Thank you very much.

Let me call on Mr. Wyden for questions.

Mr. WYDEN. Thank you, Mr. Chairman.

Dr. Henningfield, in your testimony you did not identify by brand name the smokeless tobacco products that you testified that you tested. You just listed them by letters A through E. What I'd like you to do is put that chart back up and have you identify the products that you tested by their brand name.

Mr. HENNINGFIELD. Product A is Skoal Bandits Wintergreen.

Product B——

Mr. WYDEN. Wait, let me make sure we got it. Product A is Skoal Bandit Wintergreen.

Mr. HENNINGFIELD. Product B is Skoal Long Cut Wintergreen.

Mr. WYDEN. B is Skoal Long Cut Wintergreen.

Mr. HENNINGFIELD. C is Skoal Long Cut Cherry.

Mr. WYDEN. C is Long Cut Cherry.

Mr. HENNINGFIELD. D is Skoal Long Cut Straight.

Mr. WYDEN. D is Skoal Long Cut Straight.

Mr. HENNINGFIELD. E is Skoal Original Fine Cut Wintergreen.

Mr. WYDEN. E is Skoal Original Fine Cut.

Mr. HENNINGFIELD. And F is Copenhagen Snuff.

Mr. WYDEN. F is Copenhagen.

All right. That's very helpful.

And I think what I would like to do now is bring back before the subcommittee a chart that Dr. Kessler offered this subcommittee in March. I gather that's the one that is already up there. That's the one on the left. Now, Dr. Connolly, was that a chart developed by U.S. Tobacco?

Mr. CONNOLLY. Yes. That was entered into the Marsee court case. It was Exhibit 100. And it was U.S. Tobacco Company Document Number 12017104. It was volume 5, pages 12 and 13 of the Marsee court transcript. That's a U.S. Tobacco Company document. [See p. 62.]

Mr. WYDEN. Now, Dr. Henningfield, it would be helpful if you, as an expert on addiction, could compare these two charts. Is there a similarity in the rankings based on nicotine levels that you observed in your experiment and the graduation process described by U.S. Tobacco in their chart?

Mr. HENNINGFIELD. There are products that do not correspond on the charts because they appear to be no longer on the market. However, the ordering of the products is the same as we found in the laboratory; that is, the highest dose product, the Copenhagen Snuff, is also the top of the graduation chart. The lowest dose product is the Skoal Bandits, which is on the bottom of the chart. And the Long-Cut brands are in the middle of both charts; that is, the Long-Cut brands are the mid-range dosing and appear to be in the middle of the graduation chart.

Mr. WYDEN. What is the significance, in your view, Dr. Henningfield, that U.S. Tobacco markets a line of smokeless products exhibiting natural progression or graduation in nicotine levels?

Mr. HENNINGFIELD. Well, again, without addressing intent of the company, the usefulness of that procedure is that the same kind of procedure that is useful in animal laboratories where you start animals on small doses to get them hooked or the same kind of proce-

dure that is used by illicit drug dealers who often start people on lower doses. Simply stated, if you want to get a higher percentage of people or animals hooked, you introduce them with the lower dosing products. And our data certainly demonstrate that you do have lower dosing products among these products.

Mr. WYDEN. Dr. Connolly, the company, U.S. Tobacco, has essentially argued the graduation process was really only a theory, that it was never put into actual practice by the company. Do you agree with the company's explanation?

Mr. CONNOLLY. Mr. Taddeo, in his written statement, challenged the Lotus Project. I presented the committee two documents from 1972 at the last hearing that were submitted into evidence from U.S. Tobacco product.

Mr. Taddeo asserted that the Lotus Project was written over 20 years ago, didn't mention Skoal Bandits, was not created by U.S. Tobacco and did not reflect U.S. Tobacco policy. Well, the facts are the Lotus Project was first developed by United Scandia International. It was a joint venture between U.S. Tobacco and Swedish Tobacco.

The June 2, 1972, memo was on U.S. Tobacco letterhead, and it described the activities of two working groups. The first was from Swedish Tobacco, the second one was from U.S. Tobacco.

The second Lotus document, dated July 18, 1972, were the minutes of a meeting held at Tobacco U.S. headquarters in which Mr. Louis Bantle stated he wanted a Lotus product, a smokeless tobacco portion pack for the U.S. market, and instructed the U.S. Tobacco task force to do so.

As part of that memo, the Lotus Project, which described the target group as new users, mainly cigarette smokers ages 15 to 35—this was attached to a memo from U.S. Tobacco Company headquarters talking about a Lotus Project that may have been 20 years ago but was clearly initiated by the U.S. Tobacco Company.

The strength of the new product was described as nicotine satisfaction. Nicotine satisfaction. It wasn't pleasure. It wasn't taste. It said nicotine satisfaction. The facts are these documents were created by U.S. Tobacco. They described the Lotus Project that employed a graduation strategy. And subsequently U.S. Tobacco introduced the Skoal Bandit, which was a portion pack of oral snuff into the U.S. market in 1983.

Mr. WYDEN. Dr. Henningfield, the Department of Health and Human Services has given to me a list of several hundred chemicals added to chewing tobacco, and I have been very interested over the years in all these additives and chemicals that are added to tobacco products, because the industry goes to great lengths to say that this is not of any importance to consumers and is not going to raise any health concerns.

Two of the items on this list are of particular interest to me: ammonium carbonate and sodium carbonate. I think it would be helpful, again in your capacity as a government expert on addiction, to explain to the subcommittee why these chemicals might be in these products.

Mr. HENNINGFIELD. I can't tell why a company would put them in their product but I can tell you what the effect is, and the effect here is the same as the effect as creating, for example, crack co-

caine. In that case, you mix the cocaine with sodium bicarbonate, for example, or ammonia. There are a variety of things you can mix cocain with to create free-base crack cocaine. It is not a—there's nothing tricky or mysterious or unique here. When you add a basic or alkaline high pH chemical to a substance like nicotine or cocaine, it raises the pH; it raises the free nicotine or the free cocaine. So that is the effect.

Mr. WYDEN. Let me conclude this round with a question for you, Dr. Connolly. What you have described essentially, seems to me, to be something of a ladder of addiction based on the manipulation of levels of free nicotine. At the same time, Mr. Taddeo's testimony has said, one, that no manipulation takes place and, two, that there isn't any strategy to gradually take individuals into strong nicotine products. How do you square those two points of view?

Mr. CONNOLLY. The U.S. Tobacco Company documents submitted in the Marsee court case clearly show without doubt that the company has a graduation strategy that moves users from low nicotine brands over time to higher nicotine brands as tolerance to toxic effects of nicotine occur. There's no question. Again, the United States Tobacco—the Swedish Tobacco Company would tell you that. The Danish tobacco Company would tell you that. There's no question.

Mr. WYDEN. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Wyden.

Let's just get some basic science on the record. Is it a correct statement to say that this smokeless tobacco causes oral cancer? Dr. Eriksen?

Mr. ERIKSEN. Yes, sir.

Mr. CONNOLLY. It has been the conclusion of the World Health Organization, the Surgeon General of the United States, the National Institutes of Health, as well as every major reputable health organization in this country, that smokeless tobacco causes oral cancer, nicotine dependence, as well as other mouth lesions.

Mr. WAXMAN. Is it accurate to say that the nicotine in the smokeless tobacco is addicting?

Mr. HENNINGFIELD. Yes, it is. And the Surgeon General concluded that it was in 1986. The 1986 NIH consensus conference came to the same conclusion, as later did the Institute of Medicine, the American Psychiatric Association, and World Health Organization. Again, the fact of nicotine addiction from smokeless tobacco is well established.

Mr. WAXMAN. I have received a number of letters and documents in the course of our subcommittee investigation, and I received a letter which I want to make part of the record without objection.

[The letter follows:]

ROBERT C. BYRD
HEALTH SCIENCES CENTER
WEST VIRGINIA UNIVERSITY
Mary Babb Randolph Cancer Center
Tobacco Research Center

November 22, 1994

Representative Henry A. Waxman
Subcommittee on Health & the Environment
Rm. 512 O'Neill House Office Building
Washington, DC 20515

Dear Representative Waxman:

For the record, please accept the enclosed statement for the scheduled hearings for November 29th on smokeless tobacco. Currently, I am Professor of Behavioral Medicine and Psychiatry and Director of the Tobacco Research Center, Mary Babb Randolph Cancer Center, Robert C. Byrd Health Sciences Center in Morgantown, West Virginia. I have been conducting research in the area of tobacco for the past 20 years and smokeless tobacco, specifically, the past 12 years.

Smokeless tobacco (snuff and chewing tobaccos) is a highly addictive product because it contains extraordinary high levels of nicotine. The average cigarette contains approximately 8 to 11 milligrams of nicotine with the bioavailability being .5 to 1.5 milligrams of nicotine (a cigarette averages 1 milligram). The average pinch of smokeless tobacco is a 2.5 gram pinch of tobacco and the average pinch of *Copenhagen* contains approximately 13 to 15 milligrams of nicotine for approximately 35 milligrams of nicotine. The smokeless tobacco user is exposed to more nicotine than the typical cigarette smoker. The bioavailability of smokeless tobacco is directly dependent upon the alkalinity of the smokeless tobacco. For greater buccal absorption, smokeless tobacco products are 'buffered' by the tobacco industry to alter the pH level . Because of the low pH of the burning cigarette, the smoker needs to inhale the smoke so that pulmonary absorption can occur. Only minuscule amounts of nicotine are absorbed through the buccal lining with smoking tobacco because of the low pH, whereas, if smokeless tobacco products where not buffered then virtually no absorption would take place, hence the buffering. The is a classic case where the nicotine levels are not directly being manipulated, but the environment is being altered to create an environment for greater absorption. Why are the fuss? Because it is apparent that the nicotine is the addictive agent in smokeless tobacco and without it there would be few users.

This also explains the 'starter products' i.e., sweetened smokeless tobacco, sachet types (*Bandits* and *Renegades)*, and low smokeless tobacco products. The idea is very simple--so that young adults can gradually become addicted to the product. The goal of all young users is to eventually move to *Copenhagen* because it's a manly tobacco. They begin with the lesser nicotine containing products and titrate up. It's the identical concept we use with nicotine replacement therapy (treatment for tobacco users); however, we wean users down rather than titrate users up.

By understanding the graduation process of nicotine usage of young adults, important and useful information can be retrieved from dosing data. Once we know what is contained in product i.e., chemicals; specifically the amount of nicotine per gram of tobacco, we can begin to more accurately treat the individual.

Should you or any member of your Committee wish have additional information, feel free to contact me.

Look forward to the conclusions of the Committee. Until our next contact, I remain

Healthfully yours,

Elbert D. Glover, PhD
Director, Tobacco Research Center

Mr. WAXMAN. And one of the letters was from Dr. Elbert Glover. Dr. Glover is the Director of the Tobacco Research Center at West Virginia University, and he wrote that smokeless tobacco is a highly addictive product because it contains extraordinary high levels of nicotine. And then he added, the smokeless tobacco user is exposed to more nicotine than the typical cigarette smoker. Is that an accurate statement?

Mr. HENNINGFIELD. It is a plausible conclusion. The reason is is that with the cigarette very small doses can produce a large effect because the effect is magnified when you put it in the lung. But smokeless tobacco users, very, very, very high levels of nicotine have been seen. And apparently this is because it—nicotine—comes in a little bit more steadily, so it is possible that users can tolerate getting a lot of nicotine pumped into the body with these products.

Mr. WAXMAN. And is nicotine a dangerous substance?

Mr. HENNINGFIELD. Nicotine is not only addictive but, depending on how rapidly it is delivered, it also contributes to heart disease, pregnancy problems, and other problems, again, particularly when it is given more quickly in these forms as compared to, for example, a nicotine patch which delivers the nicotine so slowly that it has a much less adverse effect on the body.

Mr. CONNOLLY. I would add, Mr. Chairman, I think the major concern with smokeless tobacco is that the age of experimentation with smokeless tobacco among preteens or teens is lower than with cigarette smoking. If you ban smoking in a school in the United States of America, they can get away using smokeless because you don't have the odor of the smoke. So the age of experimentation can be 3 years before cigarette smoking. It becomes a gateway drug.

In a sense what we do, we train teens or preteens how to affect their mood and behavior by dosing themselves with nicotine. We teach youngsters very, very bad behaviors doing that, how to deal with stress or how to gain pleasure. When you teach a 10-year-old that, in some respects, you could have a person abusing illicit drugs 10, 15 years later who was trained through starter products at a very young age.

So I think that a major concern is that we are seeing youngsters starting this product, and there is some evidence to suggest switching them to cigarette smoking when they get older and their girlfriend says, look, don't spit but smoke like me.

And we shouldn't let industries go after our young people with psychoactive chemicals. We don't have people handing out packets of Valium at rodeos or at baseball games or sitting in the back of Sports Illustrated with a can of Valium saying come to where the pleasure is or producing low-dose Valium that gets in the hands of kids that are looking for a little bit of a high. We—we don't—as a society, we shouldn't tolerate it.

Other countries, when they were faced with the introduction of this product, banned it. The entire European Economic Community has banned oral snuff. Australia has banned it. New Zealand has banned it. Because they looked at our mistakes, that we did nothing, and we created this surge of youths of a highly addictive, carcinogenic product among young people. They said how foolish can those Americans be.

Mr. WAXMAN. Well, we didn't ban it, although I thought we should have. In 1986 we passed a law saying you couldn't advertise it on television and you had to have a warning label on packaging and advertising. Yet you're telling me that 10-year-olds are getting these products? How is that happening?

Mr. CONNOLLY. States aren't enforcing the law. You can look at me as probably being a culprit on that. But the sale to the minor is really the end point in a long chain of events where somebody at some company decides to design a starter product, then initiate a marketing product using famous athletes, then advertising in sports magazines, until finally the pressure results in some 10-year-old going in and buying the product from a shelf where the store clerk doesn't care.

Mr. WAXMAN. Or does he get a sample?

Mr. CONNOLLY. A sample at a rodeo? A sample through the mail? It's the only product that you can fill out a coupon and send it in. Here are coupons for the committee. I'll put your children's names on it, and I'll guarantee you will get a free sample in about 6 weeks.

Mr. WAXMAN. So any kid can fill out that coupon and——

Mr. CONNOLLY. In the Marsee court case, the industry claimed they had handwriting experts, handwriting experts looking at it. My 4-year-old received a free sample a few years ago, and his handwriting is not all that good. He doesn't go to parochial school, I'll point out, like his father.

But I think the law we passed, the law this committee reported up, banned TV advertising, put a warning label. It should have focused probably on free sampling and event sponsorship. Those are the cornerstones for the marketing campaign and through the FDA strict regulation of how one affects nicotine by availability. If we do that, I think we have a chance of licking this problem. Otherwise, you are going to see an epidemic of mouth cancer in the next century with a lot of kids that are dipping and chewing today.

Mr. WAXMAN. Dr. Eriksen, you at the CDC under the law have to get the ingredient disclosures from tobacco manufacturers, and the law requires smokeless tobacco companies to annually provide the Secretary, through you, a specification of the quantity of nicotine contained in each such product. And that would seem to me, now that we know that it's not just the amount of nicotine—it is pH and the use of chemical additives that are put in that cause a greater percentage of the nicotine to be ingested. Do you think the annual specification should include information on the relative quantity of nicotine that's biologically available to the user? And do you think that given the importance of this information that you ought to insist on getting pH data from the companies?

Mr. ERIKSEN. I do. We have met with the smokeless tobacco industry on the nicotine reporting issue and requested that they provide nicotine levels by brand rather than just by product. The statute only requires them to produce it for product category, the way the statute was written. They have agreed in writing to provide it by brand, but we haven't asked them to provide pH levels. But I would suggest that we will do that.

They may refuse us, though. And if they refuse to provide it, then I think it would go back to your court as to requiring them

to do so in relation to the statute. But we will ask the smokeless tobacco industry to provide the pH levels as well as the nicotine levels by brand.

Mr. WAXMAN. Now, we have information about a college marketing program that U.S. Tobacco Company engaged in in order to get people to start using this product, and, without objection, we'll put in the record various documents relating to that program.

Dr. Connolly, are you familiar with the college marketing program?

Mr. CONNOLLY. I have seen documents relative to the college marketing program and their video, yes.

Mr. WAXMAN. Do you know whether it is in existence today?

Mr. CONNOLLY. I hear mixed reports. I had some baseball players from the University of Virginia tell me about 6 months ago that what they call it is a retail program. They removed the name college marketing. But that is only from a second source, so I can't affirm whether it exists or not.

Mr. WAXMAN. What does this program appear to be?

Mr. CONNOLLY. Well, the college marketing program was established in the 1980's, was on at least 200 campuses where student representatives were paid to sponsor events or go to a sporting event and basically to free sample Skoal Bandits to create a new user base.

Mr. WAXMAN. So it would be students on college campuses talking to other students to try to get them to try it.

Mr. CONNOLLY. Absolutely. Absolutely. It's basically teaching addiction in a very favorable environment and doing it very efficiently. What better place could you go if you wanted to teach people how to dose themselves with nicotine other than a college event where everybody is having fun and they are there in big numbers?

And then you've got the starter brand right there where you sit there and actually train someone how to dose themselves with nicotine who is primarily a nonuser of tobacco. So if you are a company and you want a new user base, you want to teach people how to train themselves on nicotine intake, it's probably the best place in the world to go.

Mr. WAXMAN. Now, we didn't ban this product in the mid-1980's before it had taken off, and it seemed to me we should have, because if we banned cigarettes before they had taken off we wouldn't have the problem we have in this country today. Now we have large numbers of people that are addicted to cigarettes. And, inevitably, we now have large numbers of people who have been talked into being addicted to this smokeless tobacco.

I thought your charges were pretty dramatic. As I understood your testimony, in the 1970's the only people using this product were older men, and now, in the 1990's, half the people using the product are under 21 years of age, and the increases have been pretty dramatic in the use of the product overall. Is that an accurate statement?

Mr. CONNOLLY. It is. It is really a miracle of modern marketing and modern chemistry applied to consumer products. I think it is the envy of any other Fortune 500 company, what they've done. And, you know, it's a concern because there was no regulation of the product per se or of the marketing until the—the product is

still not regulated. It is a concern, too, given the fact that those young people, if they continue to use it, will result in an increased rates of oral cancer in our country, and we are already overburdened with cancer. To make a few cents selling a tobacco product, I think it is senseless to sacrifice people's faces or lives or—for it.

Mr. WAXMAN. Well, I want to thank the three of you very much for your testimony. Members of the subcommittee may have additional questions, and we would like to ask if you would to respond in writing to the record about those issues that may come up.

Mr. HENNINGFIELD. Thank you.

[Answers to followup questions by Chairman Waxman to Mr. Henningfield:]

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
2415 RAYBURN HOUSE OFFICE BUILDING
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PHONE (202) 225-4907

December 2, 1994

Dr. Jack E. Henningfield
Chief of Clinical Pharmacology Branch
National Institute on Drug Abuse
Addiction Research Center
4940 Eastern Avenue
Baltimore, MD 21224

Dear Dr. Henningfield:

I would appreciate your assistance in responding to additional questions arising from the Subcommittee's November 29th hearing on the manipulation of nicotine in spit tobacco. During the hearing Exhibits 5A and 5B were introduced into the hearing Record. Copies of both exhibits are attached for your review.

I would appreciate your response to the following questions concerning these exhibits.

1) The October 18, 1994 Wall Street Journal quotes a U.S. Tobacco chemist saying that each U.S.Tobacco product "occupied a specific rung on the nicotine-absorption ladder" and that the company tried to control as precisely as possible the dose that each product delivered. To what extent does Exhibit 5B reflect the rungs of a nicotine-absorption ladder?

2) Exhibit 5A purports to illustrate a strategy of expanding the user base for U.S. Tobacco's spit tobacco products. Please describe for the Subcommittee whether you are aware of the origins of this chart and the extent to which the chart is consistent with the graduation process illustrated in Exhibit 5B.

3) The "Sampling" strategy described in Exhibit 5A is limited to the outer rings. Is it your view that the outer-rings represent the company's starter products? If so, why would a tobacco company need a starter product.

4) Do you see any parallels between the marketing of starter tobacco products and the way other illicit drugs like heroin and cocaine are marketed? Please explain.

Your assistance in responding to these additional questions is greatly appreciated.

With every good wish, I am

Sincerely,

Henry A. Waxman

HENRY A. WAXMAN

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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December 13, 1994

The Honorable Henry A. Waxman
Chairman, Subcommittee on
Health and the Environment
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6118

Re: Follow-up questions to my testimony, November 29, 1994 (attached).

Dear Congressman Waxman:

I am pleased to answer your four follow-up questions to my testimony on smokeless tobacco nicotine dosage manipulations.

(1) Regarding extent to which exhibit 5B reflected rungs on the nicotine absorption ladder.

Our data show that lowest nicotine dosing product that we tested (Skoal Bandits Wintergreen) is on the bottom of the "Graduation Process" chart, the highest dosing product (Copenhagen) is on the top of the chart, and Skoal Long Cut Wintergreen (which we found to be a middle dosage range product) is in the middle of the chart. My understanding is that the item labeled Skoal Wintergreen is the same as the product that we tested named Original Fine Cut Skoal Wintergreen; we found this product to be higher in nicotine dosing capability than the Long Cut products. We did not test Happy Days or Skoal/Key Natural.

(2) Origins of Bull's-eye Chart (5A) and extent to which it represents graduation process illustrated in 5B.

The Bull's-eye Chart was provided by the United States Tobacco Company to the plaintiffs in the Marsee vs. United States Tobacco Company law suit in which I served as an expert witness in 1986. This chart was provided to me by the plaintiffs attorney, Mr. Braly, to review. To my knowledge, it was not actually presented in the court. It was presented along with a variety of other documents, some of which have been made public (e.g., chart 5B), which illustrated the way that products of differing nicotine dosage levels were marketed differently. Specifically, chart 5A illustrates marketing techniques by which the "graduation process" illustrated in Chart 5B may have actually been accomplished, using sampling techniques and mass advertising with the low dose products to reach new users, and using more selected and focused advertising and marketing for the higher dosage products.

(3) Do the outer rings represent starter products? Purpose of starter product.

From a pharmacological perspective, the products in the outer rings would be much more useful as starter products than the products in the inner rings. The outer ring products are substantially lower in rapid nicotine dosing capability, they are much more heavily flavored (as their labels suggest), and the outer most product is packaged in small unit doses ("pouches") which should minimize the chance of initial use leading to overdose (colloquially referred to as "turning green").

The reason that animal researchers and illicit drug sellers initially provide lower doses to animals and people, respectively, is to reduce the chance that initial use will produce sickness and thereby discourage subsequent use. With continued use, the person or animal becomes tolerant and may increase total drug intake; over time, intake no longer continues to escalate and day to day intake may achieve relative stability. At that point, higher unit doses make it easier to obtain the amount of drug needed to sustain the addiction. For example, most daily cigarette smokers graduate from a few mg of nicotine per day by smoking 1-5 cigarettes to an average of about 30 mg nicotine per day by smoking 25-30 cigarettes. If cigarettes only delivered .1 mg nicotine, it would be necessary to smoke more than 250 per day to sustain such intake.

It is important to note that it is not critical to provide graduating dosage levels of drugs to establish addiction. Some people, and animals, who initially obtain doses that make them sick do continue to use the drugs and

escalate to addictive patterns of use. Providing graduated doses is simply a scientifically based factor that promotes the development of addiction while minimizing the risk of early overdose experiences that could discourage subsequent use by many.

(4) Parallels between tobacco starter product marketing and other illicit drugs.

In a follow-up to this letter, a subcommittee staff person (Mr. Forbes) explained that the Subcommittee also needed information on how illicit drug sellers alter drug dosage forms in ways that are similar in effect to the pH manipulation in tobacco.

As noted above, drug users and drug sellers try to avoid initially using doses that cause sickness. With experience, higher doses may not only be needed to sustain addiction, but may also be desired by the user. In South America, coca leaf chewers mix their leaves with varying amounts of alkaline ashes to increase the pH and, thus, the speed of cocaine absorption. In the U.S., it has become common for illicit drug sellers to mix cocaine powder (an acidic substance) with sodium bicarbonate (one could also use ammonia or ammonium carbonate) to produce the free base form of cocaine called crack. Many people are initiated to cocaine use by the use of the slower acting nasal powder and then escalate to intravenous use or crack smoking. People who immediately start with crack must be careful not to initially inhale too much or the experience can apparently be quite unpleasantly overwhelming.

I hope that these answers satisfactorily provide the information that you require. Please let me know if further clarification is needed.

Sincerely,

Jack E. Henningfield, Ph.D.
Chief, Clinical Pharmacology Branch

cc. Director, NIDA
Acting Scientific Director, NIDA, DIR

Mr. WAXMAN. Our next witnesses are appearing together as well.

I want to call forward Joe Garagiola, who is the national chairman of the National Spit Tobacco Education Program. He is a former major league baseball player for the St. Louis Cardinals.

Jeff Cooper is Head Athletic Trainer of the Philadelphia Phillies major league baseball team. Mr. Cooper is former president of the Professional Baseball Athletic Trainers Society.

And Rick Bender is a former smokeless tobacco user and a cancer survivor. Mr. Bender has attended several major league baseball spring training sites to warn baseball players about the health risks of spit tobacco.

Is Mr. Bender here?

Mr. GARAGIOLA. He just stepped out for a minute, Bender did.

Mr. WAXMAN. We are going to wait a minute.

Mr. GARAGIOLA. Good.

Mr. WAXMAN. We want to swear you all in at the same time.

Mr. GARAGIOLA. Hey, great.

Mr. WAXMAN. Mr. Garagiola, while we are waiting let me ask you a question.

Mr. GARAGIOLA. Yes, sir.

Mr. WAXMAN. It's not the subject of this hearing. Is there going to be a baseball season next year?

Mr. GARAGIOLA. That's one reason Curt Shilling is not here. I disagree with him. I think this is more important than negotiations. That's where he is. But I'm optimistic. I think there will be a baseball season. I would hope so. I would think those guys could live on $2, $3 million a year.

I stop to think of what I played for. Of course, I'm Jurassic Park, I know that. I'm a dinosaur. My first year in the big leagues, 1946, Mr. Ricky convinced me that it was an opportunity and so he only gave me $600 a month. Now, these guys get more meal money. It's—it's a tough negotiation, though. You know better then I do. Right?

Mr. COOPER. Don't be bashful.

Mr. GARAGIOLA. Don't be bashful. We can be creative.

Mr. WAXMAN. Let's get back to the subject at hand.

Mr. GARAGIOLA. More important.

Mr. WAXMAN. As I indicated to the first panel, our procedure at these hearings is to ask witnesses to be sworn in. You have at the table the rules of the House and the rules of the committee pamphlets that should advise you of the limits on the power of the subcommittee and the extent of your rights during your appearance today. Do you desire to be represented by counsel or advised by counsel during your appearance today?

Mr. GARAGIOLA. No.

Mr. COOPER. No.

Mr. WAXMAN. Do any of you object to appearing before us under oath?

Mr. GARAGIOLA. Love it.

Mr. WAXMAN. Well, your wish is going to be fulfilled. Please rise.

Mr. GARAGIOLA. Terrific.

[Witnesses sworn.]

Mr. WAXMAN. Please consider yourselves to be under oath.

I would like you each to identify yourself for the record.

Mr. BENDER. Rick Bender.

Mr. COOPER. Jeff Cooper, Philadelphia Phillies baseball team.

Mr. GARAGIOLA. Joe Garagiola, former player, television, tobacco—spitless tobacco. I hate the word "smokeless."

Mr. WAXMAN. We have testimony from you in writing and that will all be in the record, but we want to recognize each of you for your oral presentation, we hope around 5 minutes.

Mr. Garagiola, why don't we start with you.

STATEMENTS OF JOE GARAGIOLA, CHAIRMAN, NATIONAL SPIT TOBACCO EDUCATION PROGRAM; JEFF COOPER, HEAD ATHLETIC TRAINER, PHILADELPHIA PHILLIES; AND RICK BENDER, ORAL CANCER SURVIVOR

Mr. GARAGIOLA. Well, first of all, I want to thank you, Mr. Chairman, and I congratulate you for your battle, and I hope you continue this battle.

Now, I don't have a written statement. I wrote just some notes here, so I'm going to be all over the ballpark because the three previous witnesses were tremendous. I wish I could get them into the clubhouse. They had figures and even I understood them, the gateway and the pH and all that. I will not have that.

There is an epidemic. I know that. It's a public health problem that has not received enough attention, and I think that was brought out by the previous witnesses.

Some of the questions—is it easy to buy? You can go in the 7-Eleven store at the age of 4, and they'll sell it to you. And that bothers me that you can get it so easily.

I don't have statistics, but I've seen them. Cigarette use has declined. Spit tobacco, not smokeless tobacco—see, the tobacco industry is very sharp. Smokeless sounds harmless. Oh, it is beautiful. It's smokeless. It's harmless. It's not. Copenhagen, I'll tell you, will melt the wax in your ears if you use it. I see it on the benches of the big league when I go off into a dugout—and I've been fighting upstream for 10 years just talking to ball players.

And, finally, people like Jeff Cooper and I have tried, and we now have joined with the American Fund for Dental Health, and they are going to help us, and the Surgeon General is going to help us.

But when I walk into a ball park, and I start on them—I can name you people. They say to me, don't start on me. I brush my teeth after every game. And I say, dummy, it's not your teeth I'm worried about. It's your gums. It'll eat your gums out. It's very difficult for me to get through to 'em.

And when they don't use Copenhagen, let me tell you this, the other ball players will start on them. Hey, wimp, you want some Happy Days? You want this? Copenhagen, man, that's macho. I mean, that's Arnold Schwarzenegger. That's John Wayne. That's gunfight at the OK Corral. That's what you've got to do, Copenhagen.

And what bothers me, youngsters, they think it is a safe alternative, and it's not. And parents think that. That's one of the target groups that we have, to tell the parents that it's not a safe alternative.

And the other thing is kids use it as a symbol of being macho. They have got to have that little round can in the back here. Yeah, man, I'm Mr. Stud. Look at me. I can chew.

That is all part of it. And the tobacco industry, they don't do anything to discourage that. Smokeless tobacco, it may be smokeless, but I tell you, it will kill you.

What saddens me is that baseball, the players, are the biggest culprits. I mean, they chew, and kids chew.

Whatever town I played in—when I was with St. Louis, everybody wanted a bat like Stan Musial. In Pittsburgh, they all wanted a bat like Kiner. In Chicago, they all wanted a bat like Ernie Banks. Now they see a Dykstra on television. He gets three hits. They say, hey, maybe that'll help me. He chews.

Mickey Mantle and Hank Aaron, I wish you could have heard them. Maybe you read about them. They are against it. Hank Aaron, when he was farm director, would not put a pocket in the pants of his minor leaguers so they had no place to put the can of tobacco. That's how strong he felt about it.

Baseball's been my life. It has given me chances I never had, never dreamed of. My father and mother came over here from Italy. My father, a naturalized citizen. I made big dollars in television. Didn't make much in baseball, not like today. My record proved that. But what I am saying is this country gave me a chance through baseball, and I want—and baseball wants to eliminate it.

You can't legislate this thing out. Mr. Chairman, they were negotiating just like they did with the batting helmet. We started the batting helmet in 1952, and some of the guys says, I'm not going to wear a helmet. I just need that little liner. Then Paul Petit got hit with a throw right here wearing the helmet, didn't hurt him. Everybody ran for the helmet.

But they grandfathered it in. They ban it in the minor leagues, but in the major leagues it is part of the collective bargaining agreement. But I talked to Donald Fehr until I was blue in the face, and he agrees with me. And they will grandfather it in once they get over this hurdle of how much money they are going to make.

So much of this upsets me because baseball players give free advertising to the tobacco industry.

I have a study right here that really galls me. One game, 1993, the Phillies and the Toronto Blue Jays, you couldn't go on the Phillie bench—I was there as a broadcaster—unless you had a snorkel and fins. I mean, they were spitting all over the place. Dykstra's got a toxic waste dump in center field from spitting out there.

And every time—and when I was doing Game of the Week I used to fight with the director. What are you taking close-ups for? Because what it is is free advertising. Twenty plus 8 minutes of free advertising in one game, the 1993 Toronto-Phillies world series game, because directors thought it was cute. And kids will see that, and they'll follow it. And just try to put dollar signs to that.

What gets me, try to ask Dykstra, would you endorse tobacco? He'll say, talk to my agent. I want a zillion dollars. But yet he'll

do it for free because he's stuck on it. He's hung up on it. He's addicted to it.

We have to educate the players, too, but I'm not worried about the players. I am so worked up about this because of the kids. Eight and 10 years old?

I do a thing on the Zuni reservation which is about 60 miles from Gallup. I see these little Indian kids chew. I see them at the Navaho reservation. That bothers me. I'm talking now as a grandfather and a father.

And why am I doing it? Because I don't have statistics. And thank God we got men like this who really can prove it. I can't prove it except that I see what happened. When I first saw Rick Bender, I couldn't believe what I was seeing. Then when I talked to his wife, the anguish, 12 hours on the table because of this stuff called tobacco.

I talk to players. Tony Gwynn, big star. Why do you chew, Tony? I don't know. I like it. But I quit in the wintertime. What about when kids write to you? I don't like that. What about your family? They want me to stop. Families want these guys to stop, and they can't.

Rod Carew who even talked about when he chewed tobacco he had rationalized it in his own mind, and he's my—he's been one of my best friends, but he's now one of the biggest supporters. He said that he chewed tobacco and put a big bulge in his mouth so that it could keep his eye steady which was facing the pitcher. Here is a guy who could hit .280 with a ballpoint pen. Come on. He doesn't need all that stuff. But he rationalized it, and now he is there helping me.

Kevin Higgins, the catcher for San Diego, began chewing when he was 8 years old. Why? Because my grandpa did, and my grandpa lived till he was 92. I mean, that's the rationalization you get from adults. I'm not worried about those guys.

Len Coleman, the National League President, is behind us. Bobby Brown, former heart surgeon, he's behind us.

Once we get this out—I can't find one player who gives me good reason why he chews. The families want them to stop. And all I can say to—and I love what you said, Congressman Wyden. I just hope that we get some help. We need your help.

I just came back from Hawaii. Great gig to make a speech in Hawaii. I usually get Toledo and those kind of towns. But the American Fund for Dental Health asked me to go out there.

A lady walked up to me—and if I'm lying, I'm dying. She hands me a check. She said, I believe your message. We have to do this for the youngsters. I didn't have my glasses on. I looked down. I thought it was $100. A personal check for $10,000. I mean, I got goose pimples because I have been swimming upstream talking to players—Jeff, who is with the trainers, calling him, talking to the trainers, 200 people here, 150 here.

You don't know how happy I am to be here and to listen to what you said and to what the previous witnesses said. We need your help.

And I read about health reform and all that other stuff. I don't understand a lot of it, but I know this. That if we can control this with the kids—we got an epidemic on our hands. I don't know

about charts, but I'm telling you, when 8- and 10-year-old kids can go into 7-Eleven and buy it and chew it and dip it, we've got an epidemic. And we've got to stop it.

I hope I'm around. When I'm on that other side of the mountain—I'm going downhill. The brakes are giving out a little bit. But I'm tell you we've got to do something about it, and I need your help. I really need your help.

Thank you.

Mr. WAXMAN. Thank you very much. Very powerful testimony.

Mr. Cooper?

STATEMENT OF JEFF COOPER

Mr. COOPER. Thank you. Good morning. I would like to thank you for allowing me to attend this hearing this morning and on this most important health issue.

I come with two points of view. I'm a former addicted spit tobacco user and a representative of the Professional Baseball Athletic Trainers Society.

As I began my career in professional baseball in 1970 I was advised prior to my departure by a friend not to come home with a habit of chewing tobacco. I began almost immediately. I was introduced in the same fashion that has been so successful for the tobacco industry: preproduct, stepping-stone addiction, progressing from one brand to the next. I started with raspberry mint flavor tobaccos for the beginner, on to wintergreen flavor for the intermediates, then progressed on to the stronger products.

I used spit tobacco products without regard to health risk. I responded to the people who questioned me about my tobacco habit that I could get—habit that I could get new teeth, but a smoker could not get new lungs. As we know now, the risks are much greater.

As a certified athletic trainer I should have been one of the first to recognize the dangers associated with spit tobacco. I believe I was among the uninformed majority. I was addicted to spit tobacco for 15 years. I used it almost constantly. I even used spit tobacco in the delivery room when my first child was being born. Nicotine was a drug that my body craved, and after 10 years now I know I could easily start again.

This is a health issue we as athletic trainers deal with daily. Baseball has not been the cause of this problem. However, recently it has just begun efforts to put its own house in order. Athletic events have been associated with spit tobacco and tobacco products and used to circumvent existing legislation in regard to advertising. The incredible increase in usage of spit tobacco by minors is linked to the denial of serious health risks.

Twenty years ago many professional baseball players acquired the addiction of spit tobacco after their career began. Most users today are already addicted by the time they sign their first professional contract.

The Professional Baseball Athletic Trainers Society has been committed so it can be proactive on this issue. Our mission is to educate the athletic trainers who, in turn, can educate the athletes. PBAT's, major league baseball and other organizations are presently producing educational material working toward a tobacco-free

environment and reaching out to our communities to dismiss the idea that there is anything safe about spit tobacco.

Health care is an issue each and every one of you will soon address. I hope you will reflect upon the personal suffering, the loss of life, the drain to our resources to combat preventable diseases.

I'm honored to be here this morning, and I thank you all.

Mr. WAXMAN. Thank you very much, Mr. Cooper.

Mr. Bender.

STATEMENT OF RICK BENDER

Mr. BENDER. Thank you, sir. And I feel very privileged to be here.

I don't have a big, long, lengthy speech. In fact, most of what I'm going to do is just shoot from the hip.

Basically, I was about 12 years old when I started chewing tobacco, and there was three reasons why I did start chewing, one of them being baseball. I was a baseball player. I felt that baseball had—you know, if you were going to be a professional, you chewed tobacco.

The other reason—two others really run together, and it has to do a lot with the fact that I had friends that were starting to smoke. I didn't want to smoke. But here we had a guy on TV, Walt Garrison, saying take a pinch instead of a puff, holding up a can of Skoal, as a matter of fact, and I thought it was a safe alternative to smoking.

I was succumbing to peer pressure, sure. Didn't want to smoke so I started chewing.

So those are the reasons that I, you know, I started to chew. I chewed all the way up through high school, and I worked myself into such a frenzy, up to about a can and a half to two cans a day of chewing tobacco, at the age of 26 when I was diagnosed with an undifferentiated squamous cell.

I go around the country right now and I talk to kids all around the country, most recently in North Dakota and Montana, my home State, and that stigma that's attached to chewing tobacco being a safe alternative, the kids still think it's a safe alternative to cigarettes. And that's anything but the truth. They still think it's a safe alternative to cigarettes. After I get done talking with them, I think they have other ideas, though.

I talk to them. I tell them about the 12½ hours of surgery that I had. I try and explain to them the anguish that I did. Like Joe mentioned, we put my wife, my father sitting beside my intensive care bed crying. My little boy—when I finished all, I had a total of four surgeries. The first one was 12½ hours. The others following that were 2 to 3 hours apiece to remove half my jaw and a third of my tongue.

But I tell them about my little boy who is so embarrassed of the way dad looked that he didn't want me to pick him up at school. He wanted me to park across the street because—and I thought he was just trying to be a brave little man to show dad that he could—I can walk across the street. But he was embarrassed of the way the kids would talk about me. So those are some of the things that I talk to them about.

I've been—like I said before, I've been all over the country. And, most recently, we talked about the young kids getting the stuff. I've had cans of Skoal and a pouch of Levi Garrett chewing tobacco given to me by a principal in a little town called Mandaree in North Dakota that was taken off a second grader in school. And this happens all the time.

And I've heard testimony earlier today about graduation products, and I see things out there. A lot of kids come up to me and say, well, what is worse? Is Hawkins worse than Copenhagen? They talk—there's a lot of use of this Hawkins out there. I don't have a lot of experience with these milder brands per se because back when I started in the mid-1970's it was Happy Days, Skoal and Copenhagen; and I was right on to Copenhagen. But I hear a lot of these kids out there talking about the Cherry Skoals and the Hawkins. Those are probably the two brands that are mentioned to me the most when I talk to these kids at school.

My biggest regret, again, is what I did put my family through, too, through this whole thing. I talk to as many kids as I can. I try and get out there as much as I can. In fact, this is what I do now with my life is just go out and talk to kids. I was trying to hold down a full-time job and do this, and it just wasn't possible. And I believe the good Lord left me here for a reason and left me here being able to talk as well as I still can, even though I am missing one-third of my tongue. So there's—I decided I'm going to go out and try and give this a go.

But getting back to what Joe was saying. We need help. We need help to get out and get this message out to these kids. I do as much as I can, but I'm just one person. I just can't cover it all.

That's about all I have to say. Thank you.

Mr. WAXMAN. Thank you very much, Mr. Bender. You have said a great deal. You have shown us your own personal courage and sharing your own personal circumstances with us.

But you know—maybe you need to be told again. You have saved lives by going and talking to kids and telling them what is at stake if they are going to start with this chewing tobacco, smokeless tobacco, snuff, spitting tobacco, whatever you call it.

Mr. GARAGIOLA. Spit.

Mr. WAXMAN. I know it is called different things. Spit tobacco.

And all three of you I think have done a great deal to try to make sports figures know that they are role models for kids and the kids are going to start picking this thing up because they are influenced by it.

But you know what strikes me is how it's all being so manipulated. It's not just that kids see sports figures, and sports figures are using a product, and it's a product that is just being sold because there is a demand for it. There's a demand that's being created by a manipulation of people psychologically, kids into thinking it's a macho thing to do.

Mr. GARAGIOLA. That's right.

Mr. WAXMAN. Sports figures even thinking it's a macho thing to do. And then they use this product, and they can't quit because the nicotine in their system is being changed as they move from one starter product to a more solidly nicotine-laden product that is going to get into their system because of the chemicals that are in

the product. It is so thoroughly cynical and so much is at stake because we are talking about lives and we are talking about kids.

Mr. GARAGIOLA. We can't do it, Mr. Chairman, with just statistics.

I saw Rick Bender in a rookie league. These were the high-prized prospects, and they—in Billings, Montana. In fact, I held up the game 15 minutes so he could talk to them. And about six of those kids were chewing, and he laid one line on them. He said, look, just take a look at me. And, boy, he's got guts coming out of his—he said, take one look at me. Is this the way you want to look? This is what tobacco does.

And it was interesting to watch those kids. Almost to a man, they got rid of it. They're not going to——

PBAT has given out pamphlets. We have ideas for posters, simple things.

Bill Tuttle, a former major leaguer, how does a guy get started chewing? Because the guy next to him on a big league bench may be hurt. You got bored.

In the bull pen we used to play stupid games with tobacco. I chewed tobacco. I didn't know about this. Of course, I'm talking 1940's and 1950's. We'd sit in the bull pen. If you're on a bad team, you're out of the game by the second inning. You're bored. And so we would do games like spitting on ants, who could spit the farthest, who was the most accurate, put your shoe out there. In the meantime, we're chewing this stuff, we're chewing this stuff, and it gets to you. We have to educate the players.

Bill Tuttle started chewing because he was hurt. Harvey Keene, big chewer, was next to him. He said, give me a taste. He put it in his mouth. They removed the biggest malignant tumor in the history of the University of Minnesota Hospital.

And what we'd like to do is put out a poster. Not a fancy poster. One side, show him in a baseball uniform, the glory days. Second one—he's agreed—scar from here to here, the gory days. Spit tobacco did it. You got any more questions? That's all. And I'll get it in every clubhouse, guarantee you. I put his picture in every clubhouse when I went in this year.

That's what we have to do. We have to teach these ball players.

But we have to get to the kids when they are 8 years old, 10 years old. Because parents think, well, at least he's not smoking.

Dentists, we have to get to them. Some of them don't recognize, I don't think. I don't know.

I have a friend of mine who is chewing, an attorney. I went to his dentist. I said, just look in his mouth—you're not lying—and say, I don't like what I see. And he is going to say, what do you see? I said, tell him I don't know, but I don't like what I see. Are you chewing? That's all you have got to do. Let him think and scare it out of him. That is what you have to do.

Because, as they said so eloquently before, we got an epidemic, and it's beginning with kids. I'm telling you, it's here.

Answer any questions you got.

Mr. WAXMAN. Mr. Wyden?

Mr. WYDEN. Just one, Mr. Chairman. Like you, I think all of you have been great. And, Mr. Garagiola, you just drive it home that what this is all about is kids.

Mr. GARAGIOLA. It's people. It's people.

Mr. WYDEN. People and it's kids. I've got a 5-year-old and a 10-year-old. The room's full of parents. And that's what the country is about.

I guess I only want to ask you one question because you said it so well.

When we talk to the companies, the companies say, OK, Ron, we agree with you about the kids. They said, you know, we're not interested in kids. We're interested in marketing to adults, and they'll talk about ball players and the like. And I will come back, the chairman and others will come back and say, you know, it's really hard to see how that's the case because so much of the promotional material, the free samples and all this kind of stuff, really does glorify it for the youngsters, for the children.

If you could walk in to some of these corporate board rooms, if you could just walk on in instead of talking to Chairman Waxman and myself, walk into these corporate board rooms, what would you tell them they ought to be doing, these tobacco companies, to really make sure that our kids don't get hooked?

Mr. GARAGIOLA. The first thing I would tell them is stop selling cancer to kids. And they say we are not selling cancer to kids. That is what they're going to tell me.

I would not let ball players endorse in any shape or form, which they don't now. And I would complain—I would say to them, look, you tell me that you're not catering to kids yet you put out things. Last step is Copenhagen. And, Jeff, did they not used to send a lot of free samples to the clubhouse?

Mr. COOPER. In the 1970's we used to get 90 cans a week.

Mr. GARAGIOLA. Ninety cans a week they used to get in the clubhouse.

I think the only thing I can tell you, they are going to find 50 reasons of why they're not doing it. We've got to find 51 reasons why they are doing it. I mean, I sit here and I—they are going to give me all kinds of reasons. They might as well tell me a camel's got two humps, and that's why they do it. I don't care why. We're going to have to fight them. And they're a tough one. They are tough.

Look, they haven't done anything to me. I'm not anti-tobacco, as I heard said here before. I don't want to see kids chewing.

When I see 14—my best friend, Yogi Berra, he puts a dip in here, I slap him alongside the head. I said, what are you doing? He said, I just chew it when I play golf. I said, you don't. You're cheating. I mean, it is addictive.

And when kids do it, it bothers me. I don't think we can talk them out of it. I would like to go one-on-one with them with your help. And we'll fight 'em. And we'll educate the people. We can't legislate it. I don't expect you to legislate it. But we can educate the people. Educate the ball players.

Rod Carew chewed for 15 years, and finally it got to him to where he was sick for 6 weeks, was afraid to go to the doctor because he thought he was—had cancer. Finally went, over $100,000 worth of work in his mouth. And I said you dodged a bullet. Thank God it was just that. Now he calls everybody. That's how we do it, Congressman.

I'm sure that the chairman of the board or whoever—hey, everybody I talk to says I'm on the right track. But you know what? Until the American Fund for Dental Health and I got the Sons of Italy, who I'm talking to tomorrow, and I hope to get into their wallet—to be very honest with you, we need help. We need help. We can't just do it.

We got to get Rick Bender out. We got to get Bill Tuttle out. I'm going to do the Little League Convention. Everywhere I go—that's how I got started with—with the Romano and Associates with a Little League banquet.

Creighton Hale said, you really believe in this. Believe in it? It's killing our kids. When I see 8- and 10-year-olds can go in there, I—I can go on for a week, and I am very passionate about it.

In Arizona, where I live now, we just passed a 40 cent tax thing. They dumped $5 million in there—they, the tobacco industry—talking about the money is going to go to hospitals and bureaucracy and this and that and the other thing. I called the guy, and I said, look, we have to educate. I said, we're going to do a television program locally. I said, can you get me 8 and 10 year olds who—he said, I can get you girls that chew. Girls. Why? Peer pressure.

We have to educate, Congressman. We can't go into a guy who is making $7 zillion dollars and say to him stop doing it. But if I could get these three gentlemen into the clubhouse to say what they said about the gateway and opening up the spillway or whatever it was that they said, I mean, that made sense to me. They start off slow and a little bit more, a little bit more. Then you're hooked. I gotcha. We have to educate these ball players.

I mean, when you talk to them—I'm not going to bore you. I will name the name. Bobby Cox. I am on the Toronto bench. I walk in, and Bobby says, don't start on me, you and that tobacco. I said, Bobby, you got a sore in your mouth. He said, don't start on me. I said, don't believe me. Ask your trainer. He asked the trainer. Bobby Cox is not chewing anymore.

Doug Rader, he is telling he brushes his teeth. I said, you don't get cancer of the teeth. I said, you get it in your gums. It doesn't help you.

I did a thing at the Mayo Clinic a month ago. This is one of the worst cases I've seen. A young—24-year-old young man, handsome—I mean that sucker, if I had his hair and his build, I'd make a zillion dollars. He told me the lower lip was so raw, he put a piece of gauze in there and put the dip on the top lip, and that's why he was going to the cessation program.

I can't prove that it is addictive, but when he tells me stories like that, it is addictive. I'll ask him right now. If you were told by the doctor that the cancer was gone, would you go back to chew?

Mr. BENDER. Technically, the cancer is gone.

Mr. GARAGIOLA. All right.

Mr. BENDER. If I was told the cancer was not caused by the chewing tobacco, I would go up and get the can right now. I crave tobacco. I crave Copenhagen. I still love the smell of Copenhagen.

I have a few friends, for whatever choices they have made, decide to keep chewing tobacco. And occasionally I'll meet up with them, and I take their can and smell it. Smell that Copenhagen and tell me if you like the smell of it. But I crave it. I like the smell of it.

You know, I am still addicted to nicotine and will always be addicted to nicotine in my mind.

Mr. GARAGIOLA. Is that scary?

Mr. WYDEN. Mr. Garagiola, all I want to conclude with is to say we are going to fight and fight and fight until we win this for America's kids.

Mr. GARAGIOLA. Attaboy.

Mr. WYDEN. And, as you have said, we are going to have to educate.

Mr. GARAGIOLA. Right.

Mr. WYDEN. My son says we are going to have to legislate because we are going to have to enforce these rules against selling to minors.

Mr. GARAGIOLA. OK.

Mr. WYDEN. But I want you to know we are going to stay with this in every way possible until we get it done. We are real pleased that you are out there leading this battle, because it really is a fight for the health of America's youngsters. I think if we can get that message out, we will win.

Mr. GARAGIOLA. We will get the message out. We will win. I'll give you my home number.

Mr. WYDEN. You got it. An exchange. Thanks.

Mr. WAXMAN. And I want to echo my colleague's statement to you. I think the three of you are doing a magnificent job. It's clear that you care about this issue passionately, and you are doing the right thing by trying to educate these kids.

But it's not just the kids that need to be educated. The people that are pushing these products need to be dealt with as well.

And I just have in my mind the statement from Mr. Taddeo that he gave to us: U.S. Tobacco does not in any way manipulate or spike the nicotine levels in its tobacco products nor does U.S. Tobacco take any action to control the nicotine content of its tobacco products before, during or after the manufacturing process.

Just this year we have conducted a series of 10 hearings on tobacco. Before we started we knew a couple things. We knew from Surgeon Generals that cigarette smoking caused cancer and heart disease and lung problems. We knew that cigarette smoking was addicting. We knew that kids were the main targets because those seem to be the groups increasing in smoking and in using this so-called smokeless tobacco product.

Mr. GARAGIOLA. Spit.

Mr. WAXMAN. What we didn't know—spit tobacco.

Mr. GARAGIOLA. Attaboy.

Mr. WAXMAN. What we didn't know and what we have learned in these 8 or 9 months is that the tobacco industry knew it just as well, even though they denied the connection between their products and disease. We also learned that many people in the tobacco industry knew that nicotine was addicting, even though they denied it.

But what we've also learned is that nicotine isn't just an innocous by-product in cigarettes or spit tobacco products. We've learned that the nicotine can be manipulated for a very real purpose—getting people hooked. And that seemed to me a dramatic leap in our knowledge about the problem we are facing.

It is not just telling kids that this is a dangerous thing to use. It's to acknowledge that it is addicting and maybe made addicting even more than otherwise would be the case because of the added ingredients or the blending of tobacco products or other schemes that manufacturers have at their disposal in order to get users to continue to buy their product and add to their profits.

We also learned in the course of these hearings that it's not just the tobacco user, cigarette user that is at risk. It's the nonuser in a public place who has to breathe in someone else's tobacco smoke.

These are things we have learned up to this point. But this investigation shouldn't end here, even though this is the last hearing for this Congress. Because there's a lot more yet to know.

I'd like to have Mr. Taddeo come back. I think he should come back and tell us whether his statement was an accurate statement in light of the information we have learned today.

I don't think that the issue of cigarettes and tobacco and health is a partisan matter. In fact we had one hearing where we had the Surgeons General going all the way back to President Nixon's time, and all of them, Democratic and Republican administrations, indicated to us that tobacco use by cigarette smokers and other users and secondhand smoke was the leading cause of preventable death and disease in this country. So I would hope that this won't be the end of this activity for this subcommittee.

And for myself, and I know Mr. Wyden and others, Democrat and Republican alike in this Congress, we are not going to let this be the end of the issue. Because while you are going out and trying to tell kids about the dangers and your colleagues in the sporting professions about the dangers, we have got a job to do as well. And we are going to look for every opportunity to do our job as well.

Thank you very much for being with us, and that concludes our hearing for today. We stand adjourned.

[Whereupon, at 12:56 p.m., the hearing was adjourned.]

[Additional material submitted for the record follows.]

American Fund for Dental Health

AMERICAN FUND FOR DENTAL HEALTH
211 E CHICAGO AVE
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CHICAGO, IL 60611
(312) 787-6270
FAX (312) 787-9114

History

In 1955, during a period of unprecedented demand for dental education, leaders from the dental profession, dental schools and the dental industry established the American Fund for Dental Education. As the needs of dentistry changed, the mission of the Foundation expanded to include research and service programs. Reflecting these changes, in 1973 the name was changed to the American Fund for Dental Health.

Since its inception, the American Fund for Dental Health has played a key role in improving the dental health of the public by advancing the art and science of dentistry. As dentistry's independent national foundation, the American Fund for Dental Health has contributed more than $68 million to dental research grants, educational scholarships and fellowships, and service programs.

The Fund occupies a unique and central position within the dental community. It is the only foundation supported by the dental profession, dental schools, corporations, dental laboratories, dental organizations and the dental trade. Both a grant-making and an operating foundation, the Fund has received more than $21 million in grants from national foundations such as the Robert Wood Johnson Foundation, the W. K. Kellogg Foundation and many others.

Purpose and Mission

Governed by a volunteer Board of Directors working in concert with Trustee Advisors, the Fund represents the entire dental community. Fund-sponsored and supported programs benefit all of dentistry's constituencies and the dental health of the public.
The purpose of the American Fund for Dental Health is:

- to identify high priority problems that affect dental health, dental research, dental education and dental care services;
- to improve the health of the nation by supporting programs and projects that will expand the public's knowledge of dental and general health, disease prevention and treatment;
- to inform the public, appropriate agencies and the profession of the continuing need to support, improve and promote dental health as an integral part of total health; and
- to seek funds for programs and projects designed to achieve the purposes of the Fund and to serve as manager and/or fiscal agent for such programs and projects.

The AFDH raises nearly $2 million per year and allocates 70-90% of the funds directly to support dental research, dental education and the delivery of dental service programs. Its operations and programs conform to the highest standards and principles of organized dentistry.

211 East Chicago Avenue, Suite 820
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AMERICAN FUND FOR DENTAL HEALTH
ORAL HEALTH 2000 TOBACCO INITIATIVES

By the year 2000, 75 percent of all dentists will be expected to help their patients stop smoking or chewing tobacco, according to Healthy People 2000, the federal government's agenda for the improved health of all Americans. The American Fund for Dental Health, through its Oral Health 2000 initiative is working to help the nation achieve this goal.

Since 1955, the American Fund for Dental Health has brought together the public, private, and voluntary sectors and served as a catalyst for support and change within and through the dental and other related communities of interest. By supporting a variety of research, service and educational programs, the AFDH aims to identify and prioritize the challenges and opportunities impacting the nation's oral health. Recent programs and activities relating to tobacco cessation include:

- Sponsoring the **First International Conference on Smokeless Tobacco and Health**, in conjunction with Ohio State University.
- Funding from Block Drug, which acquired the exclusive rights to market and promote Habitrol™ nicotine transdermal patches to dental professional in the United States, to support Oral Health 2000's **efforts to educate dentists** in ways they can aid their patients in kicking the tobacco habit. With Block Drug's support, Oral Health 2000 has assembled a committee to develop tobacco cessation programs.
- Providing a grant for **The Little League Anti-Spitting Tobacco Initiative** and Educational Film for Little League Coaches and Volunteers to educate young athletes about the hazards of spit tobacco. Video tape will be available in December.
- Providing a grant for **A National Survey of Dentists' Tobacco Cessation Attitudes and Practice Behaviors**, conducted through the University of Florida and funded in part by SmithKline Beecham Consumer Brands, which recently acquired the exclusive rights to Nicorette™ gum.
- Providing funding for a National Spit Tobacco Education Program, that will promote oral health and educate Americans about oral cancer prevention and the dangers of spit tobacco use. The primary goal will be to prevent initial use of spit tobacco products by young athletes (10-17 years old). This program will involve **Major League Baseball** and baseball legends including Joe Garagiola, Hank Aaron, and Mickey Mantle.
- Develop a **public service advertisement with Charles Schulz's Peanuts** characters that will appear in the official Major League All-Star Game program.
- Through Oral Health 2000 additional **community based activities** are being undertaken by state consortia including:
  - the **screening** of adults for **oral cancer**
  - **worksite and community group lectures** and presentations educating the public on the importance of tobacco and smokeless/spit tobacco cessation

AMERICAN FUND FOR DENTAL HEALTH
Sponsored by:
American Dental Association
American Dental Trade Association
American Association Dental Schools

INDIANA UNIVERSITY

SCHOOL OF DENTISTRY

November 23, 1994

The Honorable Henry A. Waxman
Chairman, Subcommittee on
Health and the Environment
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-611 8

Dear Mr. Waxman,

As a University professor, tobacco cessation counselor and clinical researcher, I am particularly concerned about the dangers of smokeless tobacco (ST) use, especially among children and adolescents. We have conducted about 12 studies here in Indiana and have found that 8-10% of male children and adolescents in our state are regularly using S.T. These kids are not just from rural areas -- many of them are in city and suburban schools. In fact, nearly 3 million young and impressionable males in the U.S. are engaging in this hazardous health practice. There is real evidence that ST addiction can lure children into an even more dangerous behavior -- cigarette smoking.

At the Indiana University Nicotine Dependence Center, I personally treat many patients who are addicted to ST. It has been my experience that ST users are more addicted to nicotine in this form than they are to cigarettes. It is extremely difficult for many of these people to quit dipping/ chewing.

Smokeless tobacco is not a safe alternative to cigarettes. Long-term ST usage is directly correlated to an increased risk of cancer of the mouth, larynx, throat and esophagus. In short, there are significant health risks associated with ST use. Please do what you can to publicize and help control this important public health problem!

Sincerely,

Arden G. Christen

ARDEN G. CHRISTEN, DDS, MSD, MA
Professor
Director, Indiana University Nicotine Dependence Program

DEPARTMENT OF ORAL BIOLOGY

1121 West Michigan Street
Indianapolis, Indiana
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Located on the campus of
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Indianapolis

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Division of Neuroscience Research in Psychiatry
Department of Psychiatry
Medical School

Box 392 Mayo Memorial Building
420 Delaware Street S.E.
Minneapolis, MN 55455
612-626-4034

The Honorable Henry A. Waxman
Chairman, Subcommittee on Health
and the Environment
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6118

11/23/94

Dear Congressman Waxman,

I am writing to you to inform you of my concern over the use of smokeless tobacco. Much of the very praiseworthy work that you have undertaken in the tobacco area has been focused towards cigarettes. I have conducted research in cigarette smoking for 14 years and smokeless tobacco for the past 6 years. Over the course of these years, it has become increasingly clear to me the strong addictive nature of smokeless tobacco. There are several reasons that have led me to believe this addiction of smokeless tobacco. *First,* we have found that if a dip of smokeless tobacco is given to those who have abstained from the smokeless tobacco for several days, these subjects report significant stimulant-like and high effects compared to a snuff-like product without nicotine. *Second,* our studies have shown that smokeless tobacco users become physically dependent on smokeless tobacco. That is, they experience withdrawal signs and symptoms after cessation of smokeless tobacco use. In two of these studies, the signs and symptoms from smokeless tobacco were not as severe as that experienced from cigarettes. However, in a third yet unpublished study, which examined a large number of smokeless tobacco users who wanted to quit using the product (unlike our previous studies), we found the degree of withdrawal from smokeless tobacco similar to that of cigarettes. *Third,* the relapse rates that we observe among smokeless tobacco users who enter an intensive behavioral treatment are comparable if not worse than among cigarette smokers. The quit rate are for smokeless tobacco users is approximately 10% at one year, compared to 25% among cigarette smokers undergoing similar treatments.

What this information tells me is that the best way to help these smokeless tobacco users is by prevention. Factors which would facilitate prevention would include: (1) knowing the dosing levels of various brands of smokeless tobacco. Many of our smokeless tobacco users do not believe that they receive as much nicotine from smokeless tobacco as they do from cigarettes; (2) increasing the taxes on smokeless tobacco products; (3) not displaying the products among candies and prominent places in stores; (4) and having strict enforcement of laws for selling smokeless tobacco products to minors. The averages age of onset for smokeless tobacco use is in the pre-adolescent and early adolescent years.

I hope the information that I have given you will be helpful in your future deliberations. Thank you for all the efforts you have put forth in this area.

Sincerely yours,

Dorothy Hatsukami

Dorothy Hatsukami, Ph.D.
Associate Professor of Psychiatry

OREGON RESEARCH INSTITUTE
RESEARCH IN THE BEHAVIORAL SCIENCES
1715 FRANKLIN BOULEVARD · EUGENE, OREGON 97403-1983
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November 28, 1994

The Honorable Henry A. Waxman
Chairman, Subcommittee on Health and the Environment
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20525-6118

Dear Mr. Waxman,

I understand that you are holding hearings on possible regulation of smokeless tobacco roducts. I am writing you to express my professional opinions in the hope they may be useful to our committee.

I have been doing research in the use of smokeless tobacco for the past 15 years. I have done revention studies in schools and cessation studies with teens and adults. Based on my research and linical experience I would like to make some observations.

First, smokeless tobacco (moist snuff or chewing tobacco) is highly addictive, and people w are regular daily users have a difficult time in quitting. Studies show that nicotine levels in the blc of smokeless users are equal to, and often exceed, the levels achieved by regular smokers. I have worked personally with hundreds of smokeless users who are trying to quit, and it is difficult to b this addiction.

It would be very useful to have dosing information on the products so the consumer and professional can easily know how much nicotine the person is exposed to when using a snuff or chewing tobacco product. We see our young user moving from a "starter" product with low nicotine to higher nicotine products as they are more dependent on nicotine dosing. Clear information on both nicotine and ph of the product would be very helpful in assisting the quit effort.

A real concern to me is that very young children are using moist snuff or chewing tobacco. This product is perceived by them and their parents as a "safe alternative" to smoking. This early start often leads to regular use and in many cases the person switches to cigarettes when the use of snuff is not appropriate. Here in Oregon we also see young people switching to snuff use when worksite smoking restrictions prevent smoking on the job. In an era of reduced smoking, there has been a steady increase in the sale of moist snuff products.

In sum, I believe the use of smokeless is as addictive as smoking cigarettes and regular users have a difficult time in quitting. Clear labeling of products that includes the information on nicotine content and ph would be useful to users and counselors who try to help them quit. Smokeless tobac ducts are popular with young people and represent a growing addiction to tobacco products amc ople. We have a responsibility to warn people about the risks and dangers of regularly r wing tobacco. I strongly support any effort to provide public information on the cc

be of assistance, please feel free to write or call me.

Sincerely,

Herbert H. S
Research Scie

FACTSHEET

Smokeless Tobacco or Health: An International Perspective

The National Cancer Institute's Smoking and Tobacco Control Program has produced a monograph titled *Smokeless Tobacco or Health: An International Perspective*. From selected papers presented at the First International Conference on Smokeless Tobacco (ST), the monograph brings together important findings in ST research of the past few years.

More than 30 papers by experts around the world present current knowledge about

- the epidemiology of ST use,
- clinical and pathological effects of ST,
- the relation of ST to cancer,
- effects of nicotine and ST addiction,
- methods to prevent and stop ST use, and
- policies of various nations' governments toward the import and sale of ST products.

Participants in the First International Conference endorsed an extensive set of recommendations for the management of ST problems through research, education, and restrictive policies by governments and private institutions.

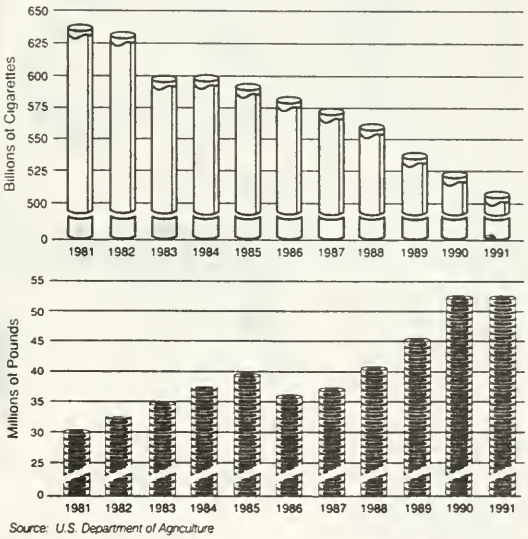
Historical Trends

Tobacco consumption has been a large part of the American lifestyle for centuries. Before the 1900's, chewing tobacco and snuff (both of which may be called smokeless tobacco, spit tobacco, or ST) were the main forms.

Cigarette smoking began to spread through American society in 1913, and after WWI, the use of manufactured cigarettes grew rapidly. As cigarettes gained in popularity, other tobacco products, especially smokeless tobacco, declined. The amount of tobacco smoked per person reached a peak in the early 1950's. Then studies began to show a link between cigarette smoking and lung cancer, filter cigarettes were introduced, and in the 1960's smoking rates started their gradual decline.

Since the late 1970's, though, use of smokeless tobacco has increased. The tobacco industry began aggressive marketing of new products, and well-known sports figures and entertainers endorsed them. ST promoters used TV to attract new users, and adolescents responded in the hundreds of thousands.

U.S. consumption of tobacco as cigarettes (top) and moist snuff (bottom), 1981 to 1991



Source: U.S. Department of Agriculture

Who Uses ST?

Worldwide, the use of smokeless tobacco is less popular than cigarette smoking. ST use is practically nonexistent in most of Europe, but it is fast becoming a major public health problem in many parts of the world. Most countries that have not banned smokeless tobacco are seeing an increase in its use.

Sweden has one of the highest rates of ST use in the world: About 35 percent of men aged 16 to 24 are occasional or regular snuff dippers. Other countries with high rates of ST use are the United States and India.

In India, ST use is high among both men and women. The most popular form of ST use is betel quid chewing. As a result of high-profile advertising for a product called *pan masala*, ST use is increasing among college-educated Indian people and those in business and management positions.

In the United States, most ST users are male—12 times as many males as females—and relatively young. The average consumer is between 18 and 30 years old, but it is not unheard of for boys as young as 8 to 10 to be regular snuff users. ST use is common among some groups of U.S. women, for instance in some Native American tribes and among elderly women in rural areas of the South. In surveys of high school and college students, about 2 percent of women reported they used ST.

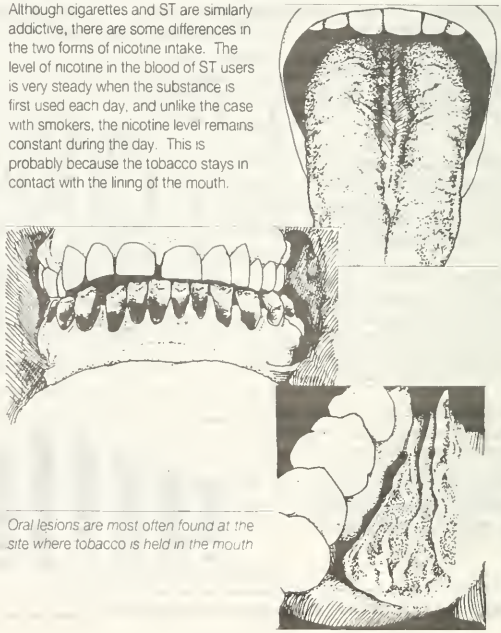
Effects of ST Use

Lesions in the mouth are common among ST users. Other common findings are inflamed and receding gums, leukoplakia (precancerous, raised, white patches), and oral cancer. Smokeless tobacco (snuff more so than chewing tobacco) can reduce the number of cells in the mouth (Langerhans cells) that work with the immune system to protect against viruses, fungi, and cancers.

Studies long ago established that use of oral snuff could cause cancer. Researchers are now learning more about how some substances in tobacco—chemicals called NNK and NNN, for example—can contribute to the development of cancer. ST contains much higher levels of these substances than are permitted in any other consumer product. These harmful chemicals may act alone or with viruses to start tumors.

Nicotine, the addictive substance in tobacco, may also play a role in the development of cancer by ST users. Treatment of oral cancers may require disfiguring surgery, and patients often have trouble afterward with chewing, swallowing, and speaking.

Although cigarettes and ST are similarly addictive, there are some differences in the two forms of nicotine intake. The level of nicotine in the blood of ST users is very steady when the substance is first used each day, and unlike the case with smokers, the nicotine level remains constant during the day. This is probably because the tobacco stays in contact with the lining of the mouth.



Oral lesions are most often found at the site where tobacco is held in the mouth

Preventing, Stopping Use of Smokeless Tobacco

Typical health education methods may not work to prevent ST use. Prevention efforts might be more successful if they mimic some of the strategies that the tobacco industry uses to win customers:

- narrow targeting of messages for susceptible groups,
- attractive packaging of educational programs, and
- the use of educators who are culturally acceptable to the target audience.

Programs to help people stop using ST have had mixed results. Many ST users are also smokers and may switch back and forth, so an ST cessation program must also address smoking behavior.

The presence of mouth lesions can be an advantage in a cessation program. Often, seeing a lesion where the tobacco is placed can prompt the ST user to try to quit.

Nicotine replacement therapies *may* help improve ST cessation rates. While nicotine gum has produced variable success rates, the transdermal nicotine patch may be more promising. Both aids are most effective, however, when they are used as part of a cessation program that addresses the behavioral and physical aspects of ST addiction.

Dentists and oral hygienists can play an important role in ST cessation. Yet very few dentists have someone in their office teach ST prevention, refer patients to cessation programs, or prescribe nicotine replacement therapy. Dentists have reported three major barriers to counseling their patients about ST use:

- lack of training in ST counseling,
- lack of insurance coverage for such counseling, and
- frustration from past attempts to counsel.

Some researchers have found that a low-intensity, 3-minute intervention can be very effective. To help with ST cessation, health care providers can use the same "4 A's" intervention recommended for smokers: *ask, advise, assist,* and *arrange.*

- *Ask* if the patient uses tobacco.
- *Advise* users to stop.
- *Assist* users with cessation—for instance, by setting a quit date, providing self-help booklets, or prescribing nicotine gum or the patch.
- *Arrange* for followup—a visit or phone call—after any cessation attempt.

As knowledge about ST use grows, it becomes clearer that, as with smoking, a two-pronged approach is needed to prevent and stop ST use. Control strategies must be aimed at the physical and social environment as well as at individual users.

Currently there is no single best approach for all ST users; different users are drawn to and affected by different programs or messages at different times. Comprehensive strategies to control tobacco use will address peer pressure and role modeling in adolescence, social skills, motivations, availability of ST and cigarettes to young people, advertising and counteradvertising, addiction and withdrawal, coping behaviors, and social norms (that is, whether tobacco use is permitted or prohibited in locations frequented by users).

By influencing the greatest number of environmental conditions for each ST user, it is possible to move him or her along the scale from not wanting to quit to thinking about quitting, to trying to quit, to—finally—success in quitting.

Public Policy

The use of ST is common in some countries, while it is virtually unknown in others.

- The World Health Organization recommends that ST be banned in countries where it has no foothold and that all countries establish a social climate that discourages ST use.
- WHO also recommends taxation, restriction on ST use in public places and at worksites, and prominent health warnings on packaging.
- Ireland passed the first national legislation banning the importation, manufacture, and distribution of oral ST. The European Community and some of its Member States have since adopted the Irish model.
- Countries where ST is banned include Israel, New Zealand, W. Australia, Hong Kong, Singapore, and Taiwan.
- In many countries where ST is still allowed, health warnings are required on product packaging and advertisements.

For more information, call 1-800-4-CANCER.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health
National Cancer Institute
Bethesda, MD 20892

US TOBACCO COMPANY RESPONSE TO LETTER DATED MAY 19, 1994

I. INTRODUCTION

This memorandum is submitted by United States Tobacco Company in response to a letter dated May 19, 1994, from the Honorable Henry A. Waxman, Chairman, House Subcommittee on Health and the Environment (the "Subcommittee"), to Joseph R. Taddeo, President, United States Tobacco Company ("USTC" or "the Company"). The letter (Attachment 1) was sent approximately one month after Mr. Taddeo's testimony on behalf of the Company before the Subcommittee on April 14, 1994. Prior to the Subcommittee's letter being sent, Mr. Taddeo provided the information requested by the Subcommittee during the April 14 hearing. (See Attachment 2, letter from Mr. Taddeo dated April 22, 1994, to Chairman Waxman).

The Subcommittee's letter, dated May 19, 1994, requested that the Company provide additional information and documents. On June 6, 1994, counsel for the Company met with Subcommittee staff and discussed the breadth of the requests and the limited time frame for responding appropriately. Subcommittee staff was advised of the method by which the Company intended to review certain files for responsive information in order to meet the Subcommittee's time frame. In a subsequent conversation with staff on July 13, 1994, counsel for the Company indicated that the Company was able to respond to the first thirteen requests in the Subcommittee's letter by July 22, 1994, and that the remaining requests (Nos. 14-23) would be responded to later in the summer. Counsel for the Company

also asked staff how it would handle documents and information submitted by the Company. Staff indicated that this issue was being discussed with the other tobacco companies, and that whatever was agreed upon with respect to their materials would also apply to USTC's documents and information.

In assembling responses to the Subcommittee's requests, counsel have spoken to individuals from the Company's executive, research, product development, quality control, and manufacturing ranks, based at the Company's headquarters in Greenwich, Connecticut; its processing and manufacturing facilities in Nashville, Tennessee; Hopkinsville, Kentucky; and Franklin Park, Illinois; and others in the Company who would be most likely to have the requested information and documentation. Counsel also have conducted a review of file labels and indices of current files retained by these individuals. Where a file label or file index suggested responsive documents, a document review was conducted. However, as discussed with the staff during the June 6, 1994 meeting, the Company did not intend to do a document-by-document and page-by-page review of the millions of documents in the Company's possession.

II. QUESTIONS AND RESPONSES

1. State whether your company supports directly or indirectly any human or animal research through entities other than the Smokeless Tobacco Research Council. In answering this question include specific and detailed information concerning both behavioral as well as biomedical research.

* * *

The Smokeless Tobacco Research Council ("STRC") is the primary organization by which the smokeless tobacco industry funds scientific research. In addition to its contributions to the STRC, the Company provides individual financial support for various scientific endeavors, as described below.[1] As a result of the budgetary process, senior management is aware of what non-STRC research is funded. In many cases the results of the non-STRC research have been published, and we have provided the pertinent citations for the Subcommittee's reference.

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[1] We have omitted here and throughout this response information concerning research funded by the Council for Tobacco Research -- U.S.A., Inc. ("CTR"), which we understand CTR representatives are providing the Subcommittee. The Company currently is a "class B" (non-cigarette manufacturer) member of the CTR, and has been since 1988. USTC has not manufactured cigarettes for approximately a decade. USTC's current annual contribution to the CTR is $5,000. Prior to this, when the Company was a "class A" member, its funding for the CTR was based on market share of cigarette sales, which was at all times less than .2% of total domestic cigarette sales.

Tony Axéll, D.D.S., Ph.D.
Lund University
Malmö, Sweden

Dr. Tony Axéll, D.D.S., Ph.D., of the Department of Oral Surgery and Oral Medicine at Lund University Dental Faculty in Malmö, Sweden, was the principal investigator on a research project entitled, "A Comparative Study Between Oral Mucosal Changes, If Any, Associated With 'Tea Bag' Snuff and Those Seen in Swedish Users of Wet Snuff." This research resulted in the following publications:

Andersson, G. Snuff-Induced Changes Associated With the Use of Loose and Portion-Bag-Packed Swedish Moist Snuff. A Clinical, Histological and Follow-Up Study. Swedish Dental Jnl. Supplement 75, 1991.

Andersson, G., Axéll, T. Clinical Appearance of Lesions Associated With the Use of Loose and Portion-Bag Packed Swedish Moist Snuff, A Comparative Study. Jnl. Oral Pathol. Med. 17: 2-7; 1989.

Andersson, G., Axéll, T., Larsson, Å., Histologic Changes Associated With the Use of Loose and Portion Packed Swedish Moist Snuff: A Comparative Study. Jnl. Oral Pathol. Med. 18: 491-497; 1989.

Andersson, G., Axéll, T., Larsson, Å. Impact of Consumption Factors on Soft Tissue Changes in Swedish Moist Snuff Users: A Histological Study. Jnl. Oral. Pathol. Med. 19: 453-458; 1990.

Larsson, Å., Axéll, T., Andersson, G. Reversibility of Snuff-Dipper's Lesion in Swedish Moist Snuff Users: A Clinical and Histological Follow-up Study. Jnl. Oral Pathol. Med. 20: 258-264; 1991.

Andersson, G., Axéll, T.m, Larsson, Å. Clinical Classification of Swedish Snuff Dippers' Lesions Supported by Histology. Jnl. Oral Pathol. Med. 20: 253-257; 1991.

This research was conducted between 1985 and 1989. USTC provided funding in the amount of $60,000.

Betty Shannon Danes, M.D.
Cornell University Medical College
New York, New York

Betty Shannon Danes, M.D., Associate Professor of Medicine and Director of the Laboratory for Cell Biology at Cornell University Medical College was the principal investigator in a research project entitled, "Genetic Risk for Tumors of the Aerodigestive Tract." This research resulted in the following publication:

Danes, B.S., De Angelis, P., Traganos, F., Ringbord, U., Nielsen, L.H., Melamed, M.R. Comparison of Anatomical Location of Squamous Cell Carcinoma Within the Oral Cavity and Oropharynx with the Incidence of *in vitro* Hyperdiploidy. *Clinical Genetics* 37: 188-193; 1990.

This research was conducted between 1987 and 1989. USTC provided funding in the amount of $64,600.

Sherwin J. Feinhandler, Ph.D.
Social Systems Analysts, Inc.
Watertown, Massachusetts

Dr. Sherwin J. Feinhandler, founder and principal of Social Systems Analysts, Inc. conducted a sociological study entitled, "The Use of Smokeless Tobacco." Interviews were conducted with consumers of smokeless tobacco products to investigate their concepts of the customs regarding use of the product, for the purpose of describing the social and cultural practices relating to smokeless tobacco. This research was described in:

> Statement of Sherwin J. Feinhandler, Ph.D. U.S. Congress, House of Representatives, Committee on Energy and Commerce, Subcommittee on Health and the Environment, Tobacco Issues: Hearings, 99th Cong., 1st Sess., 24 June and 26 July, 1985, pp. 431-445.

This research was conducted in 1984. USTC provided funding in the approximate amount of $25,780.

Steven Carson, Ph.D.
Food and Drug Research Laboratories, Inc.
Maspeth, New York

Dr. Steven Carson conducted a research project entitled, "One Year Snuff Instillation Study in Monkeys," which was designed to determine the possible effects of chronic instillation of smokeless tobacco on buccal tissue of monkeys. Tissue biopsies at the sites of instillation yielded no adverse histological findings and no abnormalities were found with respect to the body weights,

behavioral evaluations and physiological parameters of the experimental animals.

This research was conducted in 1968 and 1969. USTC provided funding in the amount of $25,000.

John P. Foreyt, Ph.D.
Baylor College of Medicine
Houston, Texas

Dr. John Foreyt, Associate Professor in the Department of Medicine at Baylor College of Medicine, was the principal investigator in a research project entitled, "Social-Psychological and Personality Factors Related to the Adoption and Maintenance of Smokeless Tobacco Use." Dr. Foreyt and Dr. Charles Spielberger of the Department of Psychology at the University of South Florida are principal co-investigators in related research that commenced in 1990 and is currently in progress entitled, "Personality Characteristics of Smokeless Tobacco Users." This research resulted in the following publication:

> Foreyt, J.P., Jackson, A.S., Squires, W.G., Hartung, G.H., Murray, T.D., Gotto, A.M. Psychological Profile of College Students Who Use Smokeless Tobacco. Jnl. Add. Behav. 18 (2): 107-116; 1993.

This research was commenced in 1984 and is continuing to date. USTC has provided funding in the amount of $335,086.

Karen A. Garber
University of Pennsylvania
School of Dental Medicine
Philadelphia, Pennsylvania

Dr. Karen Garber of the Department of Oral Pathology at the University of Pennsylvania School of Dental Medicine conducted a research project entitled, "Field Study of Oral Squamous Cell Carcinoma and Verrucous Carcinoma." This research was conducted between 1985 and 1987. USTC provided funding in the amount of $50,000.

Freddy Homburger, M.D.
Bio-Research Consultants, Inc.
Cambridge, Massachusetts

Dr. Freddy Homburger was the principal investigator in a research project entitled, "Application of Snuff to Oral Cavity of Syrian Hamster for Histological Study." The study sought to investigate the possible effects of mechanical irritation, polycyclic hydrocarbons and snuff on the facial skin, cheek pouch and oral mucosa of Syrian hamsters. This research resulted in the following publications:

Homburger, F. Mechanical Irritation, Polycyclic Hydrocarbons, and Snuff. Arch. Pathol. 91: 411-417; 1971.

Homburger, F., Hsueh, S.S. Chemical Carcinogenesis in Syrian Hamsters. Progr. Exp. Tumor Res. 16: 152-175; 1972.

This research was conducted between 1968 and 1970. USTC provided funding in the amount of $77,520.

Dr. Homburger also conducted a study with Syrian hamsters to determine whether snuff, when consumed in the diet, was carcinogenic or had any other detectable effects. This research resulted in the following publications:

Homburger, F., Hsueh, S., Russfield, A., Laird, C., Van Dongen, C. Absence of Carcinogenic Effects of Chronic Feeding of Snuff in Inbred Syrian Hamsters. Toxicol. Appl. Pharmacol. 35: 515-521; 1976.

This research was conducted between 1971 and 1973. USTC provided funding in the amount of $58,050.

Lawrence L. Kupper, Ph.D.
University of North Carolina
Chapel Hill, North Carolina

Dr. Lawrence L. Kupper was the principal investigator in a research project entitled, "Time Trends in Oral Cancer Rates" in which he examined trends in oral cancer mortality and morbidity rates from 1950 to 1980 in the United States, France, Sweden and Hong Kong. This research resulted in the following publication:

Janis, J.M., Kammerman, L., Edwards, K., Kupper, L.L. Trends in Oral Cancer Mortality in the United States, Sweden, France and Hong Kong, 1950-1980. Department of Biostatistics, University of North Carolina at Chapel Hill, Institute of Statistics Mimeo Series No. 1481, February 1985.

This research was conducted between 1983 and 1988. USTC provided funding in the amount of $105,411.

Daniel M. Landers, Ph.D.
Arizona State University
Tempe, Arizona

Dr. Daniel Landers is the principal investigator in research conducted at Arizona State University's Department of Health and Physical Education entitled, "Effects of Snuff on the Psychological and Physiological Functioning of Athletes" and "Psychological and Physiological Correlates of Performance for Smokeless Tobacco Users and Non-Users." This research resulted in the following publications:

Allen, J.K., Stern, J.R., Harris, J. Analysis of Nicotine in Blood by HPLC with Electrochemical Detection. (Abstract) Submitted for presentation at the 10th International Symposium on Column Liquid Chromatography, San Francisco, May 18-23, 1986.

Landers, D.M., Crews, D.J., Boutcher, S.H., Skinner, J.S., Gustafsen, S. The Effects of Smokeless Tobacco on Performance and Psychophysiological Response. Med. & Sci. in Sports & Exerc. 24 (8): 895-903; 1992.

Baldini, F.D., Skinner, J.S., Landers, D.M., O'Connor, J.S. Effects of Varying Doses of Smokeless Tobacco at Rest and During Brief, High-Intensity Exercise. Military Medicine 157: 51-55; 1992.

This research was conducted between 1983 and 1992. USTC provided funding in the amount of $433,306.

Dr. Landers also is the principal investigator in research currently being conducted at Arizona State University

entitled, "Extroversion as a Moderating Factor in Accounting for Performance Difference Attributed to Smokeless Tobacco." This research was commenced in 1992 and is continuing to date. USTC has provided funding in the amount of $61,579.

Mariano F. La Via, M.D.
Medical University of South Carolina
Charleston, South Carolina

Dr. Mariano La Via, Professor of Pathology and Laboratory Medicine at the Medical University of South Carolina Department of Laboratory Medicine, Division of Diagnostic Immunology, was the principal investigator in a research project entitled, "Human T-Lymphocytes Subpopulations in Dysplasia and Neoplasia." This research resulted in the following publications:

Ashman, R.B., La Via, M.F., Swanabori, S., Nahmias, A.J. Studies on the Mechanism of E Rosette Formation and Inhibition. Clin. Immunol. and Immunopath. 16 39-47; 1980.

La Via, M.F. E Rosette Inhibition by Antilymphocyte Serum in Neoplasia. In: Abstracts in Cancer Detection and Prevention, Federal Symposium on the Prevention and Detection of Cancer, Vol. 3, No. 1, 1980, Marcel Dekker, Inc., 1980.

This research was conducted from 1980 to 1981. USTC provided funding in the approximate amount of $8,000.

Dr. La Via is also the principal investigator in a research project currently being conducted at the Medical University of South Carolina in Charleston entitled, "Subtype

Response to Stress and its Significance in Immunomodulation and Morbidity." This research commenced in 1992 and is currently in progress. USTC has provided funding in the approximate amount of $126,273.

Microbiological Associates
Bethesda, Maryland

Steve R. Haworth, Ph.D. was the principal investigator in a series of four tests known as "Salmonella/Mammalian-Microsome Plate Incorporation of Mutagenicity Assay" conducted on four brands of USTC's smokeless tobacco products using five tester strains of bacteria. The results were that three of the tested brands did not result in a positive response and one of the tested brands did result in a positive response in one of the five tester strains. The tests were conducted in 1984. While records concerning expenditures are not available, it is believed that these tests were conducted at a cost to USTC of approximately $20,000.

Harry H. Mincer, D.D.S., Ph.D.
University of Tennessee
Memphis, Tennessee

Dr. Harry H. Mincer was the principal investigator in research performed at the Departments of Pathology and Oral Pathology at the University of Tennessee College of Medicine entitled, "Development of an Oral Leukoplakia Proneness Profile." This research resulted in the following publication:

Koski, O., Mincer, H.H., Development of an Oral Leukoplakia Proneness Profile. Abstract No. 1049. Office on Smoking and Health, 1980 Directory of On-Going Research in Smoking and Health, U.S. Department of Health and Human Services, Washington, D.C.

This research was conducted between 1976 and 1981. USTC provided funding in the amount of $9,104.

Dr. Mincer also is the principal investigator in research conducted at the University of Tennessee College of Dentistry entitled, "Prevalence of Oral Lesions and Tobacco Use in an Urban and Rural Population." This research resulted in the following publication:

Mincer, H., Jennings, B., Phillips, J., Somes, G., Tanner, R., Hamner, J. Comparison of Prevalences of Oral Mucosal Lesions in a Rural and an Urban Population with Evaluations of Tobacco, Alcohol, Mouthwash and Analgesic Use. Abstract. Jnl. Oral Pathol. 17 (8): 435-436; 1988.

This research was commenced in 1985 and is continuing to date. USTC provided funding in the amount of $152,711.

Erle E. Peacock, Jr., M.D.
Tulane University
New Orleans, Louisiana

Dr. Erle E. Peacock, Jr., of the Department of Surgery at Tulane University, was the principal investigator in a research project entitled, "Long Term Carcinogenicity of Saccharine in the Rat." Dr. Peacock concluded that saccharin administered as a dietary supplement to two generations of laboratory rats in a dose comparable to that ingested by the average user of smokeless

tobacco is not associated with an increased risk of bladder cancer. This research was conducted from 1978 through 1981. USTC provided funding in the amount of $37,167.

James Richardson, Ed.D.
University of Tennessee
Martin, Tennessee

Dr. James Richardson conducted research at the University of Tennessee Department of Physical Education and Health entitled, "Physiological and Psychological Aspects of Smokeless Tobacco Use." Dr. Richardson concluded that there were no significant differences between users and non-users of smokeless tobacco in demographic and physiological characteristics, nor in psychological profiles. This research was conducted between 1984 and 1986. USTC provided funding in the amount of $27,550.

Gerhard N. Schrauzer, Ph.D.
University of California at San Diego
Revelle College
La Jolla, California

Dr. Gerhard Schrauzer, Professor of Chemistry at the University of California, San Diego, was the principal investigator in a research project entitled, "Epidemiological and Etiological Aspects of Oral Cancer." This research was conducted between 1986 and 1989. USTC provided funding in the amount of $50,000.

Professor Schrauzer also conducted research at the University of California, San Diego, entitled, "Trace Elements as Risk Factors of Oral Cancer Development." The research was conducted between 1989 and 1991. USTC provided funding in the amount of $40,000.

William G. Shafer, M.D.
Indiana University School of Dentistry
Indianapolis, Indiana

Dr. William G. Shafer, Professor and Chairman of the Department of Oral Pathology at Indiana University School of Dentistry, conducted a research project entitled, "Oral Cancer Evaluation Project." Dr. Shafer reviewed oral cancer records at the Department of Oral Pathology at Indiana University School of Dentistry. This review was conducted in 1975. USTC provided funding in the amount of $540.

James F. Smith, D.D.S., M.D., Ph.D.
University of Tennessee
College of Medicine
Memphis, Tennessee

Dr. James F. Smith was the principal investigator in research conducted at the University of Tennessee Medical Units, Institute of Pathology. The study sought to elicit specific data from subject patients with respect to dental hygiene, alcohol use and other medical and socioeconomic factors for submission to

statistical analyses to determine the possible etiological significance of such factors.

Dr. Smith also conducted the following research projects: "Oral Mucosal Changes in the Choctaw Indian Tobacco User," "Fluorescent Antibody Study of the Mucous Membrane of Snuff and Tobacco Users," "Thymus Cells in the Role of Cancer Prediction" and "Latent Period Changes in Buccal Mucosal Cells of Non-Smoked Tobacco Users."

This research was conducted from 1969 to 1977. USTC provided funding in the amount of $60,509.

Southern Research Institute
Birmingham, Alabama

Dr. William J. Suling, Ph.D. was the principal investigator in a series of three tests known as "Salmonella/Mammalian-Microsome Mutagenicity Test" conducted on four brands of USTC's smokeless tobacco products. The reported results were that three of the tested brands did not result in a positive response and one of the tested brands did result in a positive response in one of the tester strains used under the experimental conditions employed.

These tests were conducted in 1984 at a cost to USTC of $16,428.

William G. Squires, Ph.D.
Texas Lutheran College
Sequin, Texas

Dr. William G. Squires was the principal investigator in research conducted at Texas Lutheran College entitled, "Effects of Smokeless Tobacco on Plasma Lipoproteins and Blood Pressure in Young Adults." This research was conducted between 1982 and 1985. USTC provided funding in the amount of $43,786.

Theodor D. Sterling, Ph.D.
Simon Fraser University
Burnaby, British Columbia, Canada

Professor Theodor Sterling of the School of Computing Science, Faculty of Applied Sciences at Simon Fraser University, is the principal investigator in a research project entitled, "Further Explanation of Lifestyle Factors and Occupational Exposure as Risk Factors of Cancer in Head and Neck Region." This research was commenced in 1992 and is continuing to date. USTC has provided funding in the amount of $93,449.

Elliott Vesell, M.D.
Pennsylvania State University
Hershey, Pennsylvania

Dr. Elliott Vesell was the principal investigator in research conducted at the Milton S. Hershey Medical Center of Pennsylvania to examine the absorption by humans of nicotine from

snuff and chewing tobacco. This research is reflected in the following publication:

Kyerematen, G.A., Dvorchik, B.H., Vesell, E.S. Influence of Different Forms of Tobacco Intake on Nicotine Elimination in Man. Pharmacology 26: 205-209; 1983.

This research was conducted between 1977 and 1980. USTC provided funding in the amount of $34,358.

Charles A. Waldron, M.D.
Dwight R. Weathers, D.D.S.
Emory University School of Dentistry
Atlanta, Georgia

Dr. Charles A. Waldron, Professor of Oral Pathology and Dwight R. Weathers, D.D.S. were the principal co-investigators in research conducted at Emory University School of Dentistry entitled, "A Prospective Study of Patients With Oral Epithelial Dysplasia With Special Reference to their Immunological and Dietary Status." This research resulted in the following publications:

Sawanobori, S., Ashman, R.B., Nahmias, A.J., Benigno, B., La Via, M.V. Rosette Formation and Inhibition in Cervical Dysplasia and Carcinoma *in Situ*. Cancer Resh. 37: 4332-4335; 1977.

La Via, M.F., Ashman, R.B., Nahmias, A.J., Sawanabori, S. Inhibition of E Rosettes by Antilymphocyte Serum in Preneoplastic and Neoplastic Disease. Abstract. Presented at the Fifth Annual Meeting of the Southeastern Cancer Research Association Proceedings, October 6-7, 1977, Atlanta, Georgia.

Kreitzman, S.N., Waldron, C.A., Weathers, D.R., La Via, M.F. Spectrum of Dietary Vitamin A Relationship to Epithelial Dysplasia. Abstract 225. Jnl. Dental Resh. 58 (Special Issue A): 149; 1979.

This research was conducted between 1976 and 1981. USTC provided funding in the amount of $81,267.

Harvard Research Project

Dr. Gary L. Huber was the principal investigator in a multidisciplinary research program conducted at Harvard University with the objective of establishing a comprehensive research facility at a leading medical school to study both -- at a basic science and applied clinical level -- the interacting chemical and biological effects of tobacco smoke on the lungs. USTC provided funding for the years 1972 to 1980 in the amount of $32,762, according to available records.

UCLA Research Project

The UCLA research program, entitled "Tobacco and Health," was a multidisciplinary research program conducted at the Center for Health Sciences at UCLA encompassing four major areas of study: (1) host defense functions with particular emphasis on the monocyte-macrophage defense system; (2) the developmental biology of cells of the blood-forming and host defense systems; (3) the treatment of human neoplastic diseases; and (4) the development of technology for insertion of new genetic information into cells and animals for the purpose of treating disease. The overall objectives of the research were: (1) to understand the normal

controls of development and function of cells of the blood-forming and defense systems of the body; (2) to understand the mechanisms underlying abnormalities of cellular development and function that cause human diseases; and (3) to apply knowledge obtained from studies of cell development and function to the treatment of human diseases with the objectives of cure or amelioration. USTC provided funding for the years 1974 to 1990 in the amount of $19,200, according to available records.

Washington University Research Project

Dr. Paul E. Lacy, Chairman, Department of Pathology, was the principal investigator in a multidisciplinary research program at the Cancer Immunology Laboratories, Washington University School of Medicine, St. Louis, Missouri. The various projects conducted as part of this program resulted in the publication of over 200 original research papers in prestigious scientific journals. USTC provided funding for the years 1971 to 1990 in the amount of $98,429, according to available records.

Chemosol Research Project

The Company believes it contributed $800 to a "Chemosol Research Project" during the period 1970 to 1973. Available Company records do not contain any information regarding the nature of this research project. The Company is aware, however, that certain research regarding a substance known as "Chemosol" was discussed at a hearing regarding cigarette labeling and advertising, held by the House Committee on Interstate and Foreign Commerce, on April 29, 1969.[2]

Southern Research Institute

The Southern Research Institute project, entitled "Biological and Biochemical Effects of Tobacco on Bee Stings," was designed to determine if, according to folklore, tobacco paste applied at the site of intradermal injection of bee venom into mice would reduce the acute toxicity of the venom. Results of the study indicated that tobacco paste, when applied to the injection site, did not alter the toxicity of the venom. USTC provided funding in 1985 to SRI in the amount of $21,955, according to available records.

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[2] See Cigarette Labeling and Advertising -- 1969: Hearings on H.R. 643, H.R. 1237, H.R. 3055, and H.R. 6543 Before the Committee on Interstate and Foreign Commerce, 91st Cong., 1st Sess. 893 (1969) (statements of Dr. Terry B. Hudson and Dr. Benedict J. Duffy, Jr.).

2. Can you assure the Subcommittee that the research projects referenced in the STRC Annual Reports represent a full disclosure of all research supported by the STRC directly or through third parties? If not, provide a detailed description of all research supported by STRC funding for the period 1982-1993. Such description should include a detailed abstract identifying the name of the investigator, the location where the research was performed, the purpose of the research, conclusions, funding provided to carry out the work, and whether any of the research was ever incorporated, directly or indirectly, into any marketed product or marketing campaign?

* * *

There are additional research projects funded through the STRC that are not referenced in that organization's Annual Reports. These projects, for the period 1982-1993, are described below. The research was not incorporated into any USTC-marketed product or marketing campaign.

William F. Ganong, M.D.
University of California
San Francisco, California

Dr. William Ganong, Professor and Chairman of the Department of Physiology and Director of the Neuroendocrine Laboratory at the University of California, San Francisco, was the principal investigator in research projects entitled, "Neuroendocrine Components in the Regulation of Blood Pressure and the Production of Hypertension" and "A Study of the Regulation of Blood Pressure and the Production of Hypertension." This research resulted in the following publications:

Ganong, W.F. Control of Aldosterone Secretion. In: Steroid Modulation of Neuroendocrine Function and Sterols, Steroids, and Bone Metabolism. L. Martini, G. Gordon, F. Sciara, Eds., pp. 111-122, Elsevier, Amsterdam, 1984.

Alber, R.H., Ganong, W.F. Pharmacological Evidence that the Sympathetic Nervous System Mediates the Increase in Renin Secretion Produced by para-Chloroamphetamine. Neuropharmacology 23: 1237-1240; 1984.

Ganong, W.F., Porter, J.P. Bahnson, T.D., Said, S.I. Peptides and Neurotransmitters that Affect Renin Secretion. Jnl. Hypertension 2 (Suppl. 1): 75-82, 1984.

Ganong, W.F. Neuropeptides in Cardiovascular Control. Jnl. Hypertension 2 (Suppl. 3): 15-23; 1984.

Ganong, W.F. Neuroendocrine Responses to Injury. In: The Scientific Basis for the Care of the Critically Ill, R.A. Little and K.N. Frayn, Eds. pp. 61-73, Manchester University Press, Manchester, 1986.

Ganong, W.F. The Neuroendocrine System. In: Neuroregulation of Autonomic, Endocrine and Immune Systems. R.C.A. Frederickson and H.C. Hendrie, J.N. Hingtgen, M.H. Aprison, Editors. Martinus-Nijhof, 1986.

Porter, J.P., Thrasher, T.N., Said, S.I., Ganong, W.F. Role of Vasoactive Intestinal Peptide in the Regulation of Renin Secretion. Amer. Jnl. Physiol. 249: F84-F89; 1985.

Ganong, W.F. The Brain Renin-Angiotensin System, 1983-1985. In: Brain Peptides Uptake, D.T. Krieger, M. Brownstein and J. Martin, Eds. pp. 215-229. Wiley, New York, 1986.

Gotoh, E., Bahnson, T.D., Alper, R.H., Ganong, W.F. Role of the Hypothalamus in the Regulation of Renin Secretion in Rats. Abstract. The Physiologist 28: 331; 1985.

Ganong, W.F., Gotoh, E., Murakami, K., Steele, M.K. Neuropeptides, Cardiovascular Homeostasis and Hypertension. Japanese Jnl. Hypertension 8: 55-70; 1986.

Alper, R.H., Deschepper, C.F., Ganong, W.F. Effect of Hypophysectomy on Dipsogenic Stimuli: Evidence for Angiotensin Supersensitivity. Amer. Jnl. Physiology 251: R53-R58; 1986.

Gotoh, E., Murakami, K., Golin, R., Ganong, W.F. Hypothalamic Regulation of Plasma Renin Activity. (Abstract) Abstracts of the 1st International Congress of Neuroendocrinology, p. 86; 1986.

Ganong, W.F., Murakami, K. The Role of Angiotensin II in the Regulation of ACTH Secretion. Ann. NY Acad. Sci. 512: 176-186; 1987.

Gotoh, E., Murakami, K., Bahnson, T.D., Ganong, W.F. Role of Brain Serotonergic Pathways and Hypothalamus in Regulation of Renin Secretion. Am. Jnl. Physiol 253: R179-R185; 1987.

Murakami, K., Ganong,W.F. Site at Which Angiotensin II Acts to Stimulate ACTH Secretion *In Vivo*. Neuroendocrinology 46: 231-235; 1987.

Murakami, K., Ganong, W.F. Effect of Posterior Hypothalamic Knife Cuts (PHC) on Corticotropin Releasing Hormone (CRH)-ACTH Secretion Induced by Stress. (Abstract; in Japanese) Folia Endocrinologia Japonica 63: 268; 1987.

Gotoh, E., Golin, R.M.A., Ganong, W.F. Role of the Dorsal Raphe Nucleus and the Hypothalamic Ventromedial Nuclei in the Regulation of Renin Secretion. (Abstract) ASGSB Bulletin 1: 24; 1988.

Deschepper, C.F., Ganong, W.F. Renin and Angiotensin in Endocrine Glands. In: Frontiers in Neuroendocrinology Volume 10. L. Martini and W.F. Ganong, Editors. pp. 79-98, Raven Press, New York; 1988.

Gotoh, E., Golin, R.M.A., Ganong, W.F. Relation of the Ventromedial Nuclei of the Hypothalamus to the Regulation of Renin Secretion. Neuroendocrinology 47: 518-522; 1988.

Porter, J.P., Ganong, W.F. Vasoactive Intestinal Peptide and Renin Secretion. Ann. NY Acad. Sci. 527: 465-477; 1988.

Golin, E., Gotoh, R.M.A., Said, S.I., Ganong, W.F. Pharmacological Evidence that the Sympathetic Nervous System Mediates the Increase in Renin Secretion Produced by Immobilization and Head Up Tilt in Rats. Neuropharmacology 27: 1209-1213; 1988.

Gotoh, E., Golin, R.M.A., Ganong, W.F. Neural Mechanisms Affecting the Secretion of Renin and Angiotensinogen. (Abstract) 8th Intl. Congress of Endocrinology, Kyoto, Japan, p. 557; 1988.

Ganong, W.F. Angiotensin II in the Brain and Pituitary: Contrasting Roles int he Regulation of Adenohypophyseal Secretion. Hormone Research 31: 24-31; 1989.

Ganong, W.F., Deschepper, C.F., Steele, M.K., Intebi, A.D. The Renin-Angiotensin System in the Anterior Pituitary of the Rat. Am. Jnl. Hypertension 2: 320-322; 1989.

Murakami, K., Akana, S., Dallman, M.F., Ganong, W.F. Correlation Between the Stress-Induced Transient Increase in Corticotropin Releasing Hormone Content of the Median Eminence of the Hypothalamus and Adrenocorticotropic Hormone Secretion. Neuroendocrinology 49: 233-241; 1989.

Ganong, W.F. Renin Secretion and 5-Hydroxytryptamine. In: Cardiovascular Pharmacology of 5-Hydroxytryptamine: Prospective Therapeutic Applications. P.R. Saxena, D.I. Wallis, W. Wouters, and P. Bevan, Editors. pp. 329-337, Kluwer Academic Publishers, Derdrecht, The Netherlands; 1990.

Intebi, A.D., Flaxman, M.S., Ganong, W.F., Deschepper, C.F. Angiotensinogen Production by Rat Astroglial Cells *In Vitro* and *In Vivo*. Neuroscience 34: 545-554; 1990.

Tkacs, N.T., Kim, M., Dezon, M., Hargrave, B., Ganong, W.F. Pharmacological Evidence for Involvement of the Sympathetic Nervous System in the Increase in Renin Secretion Produced by a Low Sodium Diet. Life Sciences 47: 2317-2322; 1990.

Ganong, W.F., Kjos, T., Shackelford, R., Tkacs, N., Gotoh, E. Evidence that Neural Control of Circulating Angiotensinogen is Mediated by Thyroid Hormones. (Abstract) ASGSB Bulletin 4: 84; 1990.

Golin, R.M.A., Keil, L.C., Ganong, W.F. The Effect of Head-Up Tilt on Vasopressin Secretion and Arterial Pressure in Anesthetized Rats. Neuroendocrinology 54: 42-48; 1991.

Deschepper, C.F., Ganong, W.F. Distribution of Angiotensinogen Immunoreactivity in Rat Anterior Pituitary Glands. Proc. Soc. Exptl. Biol. Med. 197: 304-309; 1991.

Golin, R.M.A., Gotoh, E., Keil, L.C., Shackelford, R.L., Ganong, W.F. Lack of Effect of Vasopressin Replacement on Renin Hypersecretion in Brattleboro Rats. Amer. Jnl. Physiology, 257: R1117-R1122; 1989.

Ganong, W.F. Neural Mechanisms Regulating Renin Secretion. (Abstract) Proceedings of AAAS Annual Meeting, Abstracts of Papers, pp. 60-61, San Francisco, 1989.

Ganong, W.F. Angiotensin II as a Neuropeptide Regulator. (Abstract) Proceedings of XXXI Int'l Congress of Physiological Sciences, Helsinki, Finland, p. 42; 1989.

Kjos, T., Gotoh, N., Tkacs, N., Shakelford, R., Ganong, W.F. Neuroendocrine Regulation of Plasma Angiotensinogen. Endocrinology 129: 901-906; 1991.

Gryler, E.C., Tkacs, N.C., Ganong, W.F. Role of the Ventromedial Nuclei of the Hypothalamus in the Regulation of Renin Secretion. (Abstract) ASGSB Bulletin 5: 54; 1991.

Ganong, W.F., Tkacs, N.C., Gryler, E.C. Renin as a Stress Hormone. In: Stress, Neurochemical and Molecular Approaches. R. Kvetnansky, R. McCarty and J. Axelrod, Editors. Gordon and Breach, 1991.

This research was conducted from 1983 through 1992. USTC provided funding in the amount of $158,400. The results of this research have not been incorporated into any USTC-marketed product or marketing campaign.

Stephen N. Kreitzman, Ph.D.
Emory University School of Dentistry
Atlanta, Georgia

Dr. Stephen Kreitzman, Director of the Center for Nutrition and Dental Health at Emory University School of Dentistry was granted financial assistance for the maintenance of the Center for Nutrition and Dental Health for the period 1982 through 1983. USTC provided funding in the amount of $13,430. The results of this research have not been incorporated into any USTC-marketed product or marketing campaign.

Mariano F. La Via, M.D.
Medical University of South Carolina
Charleston, South Carolina

Dr. Mariano La Via, of the Medical University of South Carolina's Department of Laboratory Medicine, Division of Diagnostic Immunology, was the principal investigator in a research project entitled, "Human T-Lymphocytes Subpopulations in Dysplasia and Neoplasia." This research has resulted in the following publications:

Misefari, A., Venza-Teti, D., Teti, G., La Via, M.F., Rust, P.F. Spontaneous Rosetting Characteristics of Prostaglandin (PG)-Treated Lymphocytes from Patients with Solid Neoplasias. Clin. Immunol and Immunopathol. 18: 85-94; 1981.

La Via, M.F., Cillari, E., Di Gesu, G., Palmeri, S., Lio, D., Salerno, A., Li Voti, P. Modification of a Lymphoid Cell Subset in Patients with Breast Cancer. Abstract 64. Jnl. Reticuloendothelial Soc. 32 (1): 73; 1982.

Cillari, E., Di Gesu, G., Palmeri, S., Lio, D., Salerno, A., Li Voti, P., La Via, M.F. Double-Rosetting Technique for the Detection of Fcμ Receptor-Positive T Lymphocytes. Diagnostic Immunol. 1: 80-86; 1983.

La Via, M.F., Gabrielli, A., Teti, G. Requirements for the Generation of Anti-Sheep Erythrocytes (SRBC) Plaque Forming Cells (PFC) in Human Lymphocyte Cultures. Abstract 3825. Fed. Proc. 42 (4): 945; 1983.

La Via, M.F., Gabrielli, A., Silver, R., Teti, G. Fcμ Receptor-Mediated Regulation of B Lymphocyte Response to Antigen. J. Leukocyte Biology 36 (2): 233-34; 1984.

La Via, M.F., Gabrielli, A., Silver, R., Teti, G. Fcμ Receptor-Mediated Regulation of B Lymphocyte Response to Antigen. Abstract 2913. Fed. Proc. 48 (7): 1915; 1984.

La Via, M.F., Misefari, A., Venza-Teti, D., Teti, G., Gabrielli, A., Pavese, I. Depression of Direct Plaque-Forming Cell Response in Mouse Spleen Cell Cultures by Aggregated IgG2b-Induced Factors. Immunology Letters 8 (4): 165-168; 1984.

La Via, M.F., Rust, P.F., Weathers, D.R., Norton-Koger, B., Peeler, H., Kreitzman, S.N. Inhibition of E Rosetting and of OKT 11 in Patients with Oral Dysplasia and Neoplasia. Cancer Detect. and Prev. 11 271-277; 1988.

This research was conducted from 1982 to 1992. USTC provided funding in the amount of $256,119. The results of this research have not been incorporated into any USTC-marketed product or marketing campaign.

Dr. La Via also was awarded a fellowship entitled, "Study of Antibodies to Type II Collagen Induced In Vitro Stimulating Peripheral Blood Lymphocytes from Rheumatoid Arthritis Patients with Collagen II Coupled to Sheep Red Blood Cells." The fellowship was awarded in 1985. USTC provided funding in the amount of

$8,850. The results of this research have not been incorporated into any USTC-marketed product or marketing campaign.

Arthur Mashberg, D.D.S.
University of Medicine and Dentistry of New Jersey
New Jersey Medical School
Newark, New Jersey

Dr. Arthur Mashberg, Professor of Surgery at the University of Medicine and Dentistry of New Jersey, is conducting a research program entitled, "Therapeutic and Prophylactic Effects of 13-Cis-Retinoic Acid in the Management of Squamous Neoplasia of the Oral Cavity and Oropharynx." This research was commenced in 1990 and is continuing to date. USTC has provided funding in the amount of $301,776. The results of this research have not been incorporated into any USTC-marketed product or marketing campaign.

Erle E. Peacock, Jr., M.D.
Tulane University
New Orleans, Louisiana

Dr. Erle E. Peacock, Jr., of the Department of Surgery at Tulane University, was the principal investigator in a research project entitled, "Long Term Carcinogenicity of Saccharine in the Rat." Dr. Peacock concluded that saccharin administered as a dietary supplement to two generations of laboratory rats in a dose comparable to that ingested by the average user of smokeless tobacco is not associated with an increased risk of bladder cancer.

This research was conducted from 1981 to 1982. USTC provided funding in the approximate amount of $6,600. The results of this research have not been incorporated into any USTC-marketed product or marketing campaign.

Theodor D. Sterling, Ph.D.
Simon Fraser University
Burnaby, British Columbia, Canada

Professor Theodor D. Sterling, of the School of Computing Science, Faculty of Applied Sciences at Simon Fraser University, was the principal investigator in a research project entitled, "Life Style Factors and Occupational Exposure as Risk Factors in the 1985 National Mortality Followback Survey." The research resulted in the following publication:

> Sterling, T.D., Rosenbaum, W.L., Weinkam, J.J. Analysis of the Relationship between Smokeless Tobacco and Cancer Based on Data From the National Mortality Followback Survey. Jnl. Clinical Epidemiol. 45 (3): 223-231; 1992.

This research was performed in 1990 and 1991. USTC provided funding in the amount of $66,558. The results of this research have not been incorporated into any USTC-marketed product or marketing campaign.

Dwight R. Weathers, D.D.S.
Emory University School of Dentistry
Atlanta, Georgia

Dr. Dwight R. Weathers was awarded a fellowship grant entitled, "Fellowship Grant to Support Basic Research in Oral Neoplasia" for the period 1982 through 1984. USTC provided funding in the amount of $13,200.

Dr. Weathers also was the principal investigator in research conducted at Emory University School of Dentistry entitled, "A Prospective Study of Patients With Oral Epithelial Dysplasia With Special Reference to their Immunological and Dietary Status." This research resulted in the following publications:

Sawanobori, S., Ashman, R.B., Nahmias, A.J., Benigno, B., La Via, M.V. Rosette Formation and Inhibition in Cervical Dysplasia and Carcinoma *in Situ*. Cancer Resh. 37: 4332-4335; 1977.

La Via, M.F., Ashman, R.B., Nahmias, A.J., Sawanabori, S. Inhibition of E Rosettes by Antilymphocyte Serum in Preneoplastic and Neoplastic Disease. Abstract. Presented at the Fifth Annual Meeting of the Southeastern Cancer Research Association Proceedings, October 6-7, 1977, Atlanta, Georgia.

Kreitzman, S.N., Waldron, C.A., Weathers, D.R., La Via, M.F. Spectrum of Dietary Vitamin A Relationship to Epithelial Dysplasia. Abstract 225. Jnl. Dental Resh. 58 (Special Issue A): 149; 1979.

This research was conducted from 1981 through 1988. USTC provided funding in the amount of $368,478. The results of this research have not been incorporated into any USTC-marketed product or marketing campaign.

3. In your letter of April 22, you indicate USTC does not have documents regarding "tests, reports and notes regarding in-house animal laboratory testing." Between 1960-1994 has USTC supported in-house or through third parties animal laboratory testing? If documents concerning such work do not exist, provide a written description of such laboratory testing including the location, purpose and outcome of each such research project, and the amount of funding provided to carry out the work.

* * *

USTC has not conducted or supported in-house animal laboratory testing, and therefore has no documents or other information concerning such laboratory testing. The Company's responses to Questions One and Two, above, describe third-party animal laboratory research funded by USTC. USTC is submitting to the Subcommittee final reports found in the Company's files for projects which did not result in a publication. (See Attachment 3). Also responsive to Question Three is the research set forth in the STRC's Annual Reports, which the Company provided to the Subcommittee on April 22, 1994, and research contained in the CTR Annual Reports, which we understand will be provided to the Subcommittee by CTR representatives.

5. Between 1980-1994 has USTC conducted or supported through an organization other than STRC research into the development of nicotine analogs? If so, provide the Subcommittee a detailed description of this research including the specific chemical studied, the location and outcome of each research project.

* * *

The Company has not conducted or supported research into the development of what others have characterized as nicotine substitutes, so-called "analogs," apart from possible funding through the STRC to the extent any has been done.[4]

4. In your letter of April 22 you indicate USTC does not have documents regarding "in-house 'human studies to measure nicotine levels in blood and studies related to nicotine addiction'." Between 1960-1994 has USTC supported in-house or through third parties (other than SCRC) research or testing involving the measurement of nicotine levels in blood? If documents concerning such work do not exist, provide a written description of such laboratory testing including the location, purpose and outcome of such research, and the amount of funding provided to carry out the work.

* * *

USTC has not supported or conducted in-house research or testing concerning measurement of nicotine levels in blood. It therefore has no documents or other information concerning such research or testing. Company-supported research by third parties on this subject is referenced in USTC's response to Question One, above.[3]

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[3] As noted above, this response does not account for possible CTR funding into this area. See footnote 1, above.

[4] As noted above, this response does not account for possible CTR funding into this area. See footnote 1, above.

6. Has USTC conducted or supported behavioral or market research relating to the tobacco preferences of individuals between the ages of 18 and 34? Provide the Subcommittee with a copy of all such research for the period 1970-1994.

* * *

USTC, on an ongoing basis, conducts market research relating to the tobacco preferences of adult consumers, including individuals between the ages of 18-34.

To meet the Subcommittee's time frame, the Company is producing representative samples of the types of research it conducts. These samples were selected because they provide a good overview of research covering more than a decade. Included are reviews which summarize market research conducted by or on behalf of USTC from 1982 to 1990; other market research conducted from 1990 to 1993 is also included. (See Attachment 4).

FOOTNOTES TO ATTACHMENT 5
Percent Nicotine by Weight of Smokeless Tobacco Products
Manufactured by United States Tobacco Company

[1] Through June 24, 1994

[2] Product discontinued at end of 1988.

[3] Product first distributed in 1989; product discontinued in 1993.

[4] Product discontinued in 1989.

[5] Product first distributed in 1989.

[6] Product first distributed in second half of 1993.

[7] Product first distributed in second half of 1993. 1993 nicotine data for Skoal Long Cut Spearmint were determined to be erroneous due to a methodological error and therefore were not included in the chart. Error was found and corrected in 1994.

[8] Brand sold to another company in 1987.

ATTACHMENT 5

Percent Nicotine by Weight of Smokeless Tobacco Products

Manufactured by United States Tobacco Company

07001

PRODUCT	1987			1988			1989			1990			1991			1992			1993			1994 [1]		
	MEAN	LOW	HIGH	MEAN	LOW	HIGH	MEAN	LOW	HIGH	MEAN	LOW	HIGH	MEAN	LOW	HIGH	MEAN	LOW	HIGH	MEAN	LOW	HIGH	MEAN	LOW	HIGH
COPENHAGEN	1 41	1 17	1 68	1 33	1 08	1.45	1 36	1 23	1 45	1.34	1 26	1 64	1 38	1 23	1 58	1 32	1 21	1 39	1.38	1 28	1 45	1 37	1 28	1 43
GOOD LUCK [2]	1 22	1 03	2 20	1 09	95	1 17																		
HAPPY DAYS	1 48	1 18	1 86	1 44	1 29	1 69	1 62	1 39	1 72	1 54	1 39	1 89	1.39	1 28	1 49	1 41	1 29	1 51	1 45	1 34	1 58	1 49	1.42	1 81
KEY	1 46	1 32	1 63	1 36	1 31	1 43	1 36	1 25	1 55	1 37	1 22	1 49	1 30	1 29	1.41	1 35	1 28	1.41	1 34	1.30	1 74	1 36	1 29	1 40
RIGHT CUT	1 63	1 46	1 82	1 50	1 29	1 71	1 64	1 38	1 89	1 43	1 30	1 58	1 56	1 38	1 86	1 64	1 51	1 77	1 57	1 47	1 68	1 71	1 83	1 81
SELECT Menthol [3]							1.01	82	1.19	93	82	1 03	90	85	96	.91	82	98	93	86	98			
SELECT Regular [3]							1.22	1 12	1 31	1 15	1 00	1 34	1 11	98	1 23	1 13	90	1 22	1 07	92	1 17			
SEAL [4]	1 83	1 08	1 80	1 55	1 45	1 81	1 65	1 46	1 81															
SKOAL BANDITS Classic [5]							1 15	1 00	1 25	1 14	95	1 30	1 10	98	1 25	1 14	95	1 24	1 07	88	1 22	1 11	1 05	1 15
SKOAL BANDITS Mint	1 02	88	1 13	98	91	1 05	97	90	1 07	97	83	1 12	93	86	99	92	87	98	92	88	97	92	88	96
SKOAL BANDITS Straight	1 03	90	1 03	1 00	91	1 16	1 17	1 01	1 35	1 15	99	1 26	1 11	98	1 25	1 11	1 01	1 25	1 05	95	1 18	1 09	98	1 15
SKOAL BANDITS Wintergreen	1 03	80	1 13	97	89	1 04	96	85	1 04	95	84	1 04	92	82	1 01	91	86	98	92	87	1 03	90	86	95
SKOAL LONG CUT Classic	1 47	1 32	1 67	1 41	1 28	1 67	1 48	1 36	1 81	1 51	1 34	1 64	1 34	1 26	1 46	1 35	1 20	1 45	1 41	1 32	1 48	1 43	1 36	1 49
SKOAL LONG CUT Mint	1 42	1 04	1 64	1 37	1 00	1 63	1 43	1 19	1 64	1 48	1 31	1 63	1 31	1 22	1 44	1 32	1 24	1 42	1 38	1 29	1 43	1 40	1 32	1 60
SKOAL LONG CUT Straight	1 44	1 29	1 67	1 39	1 25	1 67	1 47	1 20	1 81	1 48	1 04	1 64	1 33	1 25	1 45	1 33	1 24	1 39	1 37	1 28	1 46	1 41	1 34	1 50
SKOAL LONG CUT Wintergreen	1 42	1 21	1 62	1 38	1 19	1 55	1 44	1 33	1 64	1 49	1 32	1 80	1 32	1 24	1 45	1 32	1 22	1 42	1 32	1 28	1 43	1 40	1 33	1 48
SKOAL LONG CUT Cherry [6]																			1 39	1 36	1 49	1 39	1 33	1 50
SKOAL LONG CUT Spearmint [7]																						1 40	1 36	1 48
SKOAL Fine Cut	1 41	1 24	1 57	1 35	1 28	1 46	1 33	1 21	1 42	1 35	1 24	1 43	1 36	1 28	1 47	1 34	1 26	1 58	1 32	1 28	1 43	1 34	1 29	1 38
WB CUT	2 63	2 14	2 83	2 70	2 36	3 41	3 35	2 60	4 48	3 31	2 52	4 64	2 86	2 40	2 82	2 87	2 32	2 96	2 74	2 54	3 14	2 77	2 69	2 98
BRUTON	2 19	1 83	2 78	2 11	1 82	2 41	2 16	1 86	2 78	2 37	1 05	2 70	2 11	1 87	2 46	2 04	1 80	3 25	1 96	1 70	2 37	1 89	1 58	2 16
C.C.	1 87	1 69	2 10	1 79	1 58	1 98	1 79	1 57	1 97	1 84	1 63	2 88	1 62	1 44	1 94	1 41	1 15	1 63	1 34	1 22	1.60	1 53	1 47	1 58
DEVOE Sweet	1 87	1 69	2 10	1 79	1 58	1 98	1.79	1 57	1 97	1 84	1 63	2 88	1 62	1 44	1 94	1 41	1.15	1 63	1 34	1 22	1.60	1 52	1 47	1 58
OLD MILL [2]	2 11	1 72	2 44	2.22	1.97	2.44																		
RED ROSE [2]	99	91	1 08	1 12	1 06	1 35																		
RED SEAL	2 05	1 71	2 27	2 00	1 71	2 20	1 89	1.68	2 25	2 05	1 28	2 31	1 96	1 78	2 31	1 67	1 49	1 90	1 59	1 52	1.85	1 88	1 40	1.75
ROOSTER	2 11	1 72	2 44	2 22	1 97	2 44	1 99	1 70	2 50	2 19	85	2 63	2 22	2 04	2 30	1 91	1 78	2 14	1 82	1 72	2 30	1 81	1.79	1 84
STANDARD	2 27	2 06	2 43	2 47	2 28	2 84	2 25	2 08	2 73	2 00	1 82	2 47	2 38	2 37	2 40	2 20	2 08	2 28	2 14	2 02	2 27	2 14	2 13	2 17
WINTERS CLIPPINGS [8]	1 29	1 19	1 58																					
HAPPY JIM [9]	48	41	57																					

7. Provide for the Subcommittee a description of the specific manufacturing steps in which the nicotine or alkaloid level for each of your company's oral tobacco products are measured. In addition, provide a description of the relative nicotine levels by weight and as a percentage for each brand of oral tobacco manufactured by USTC during the period 1980-1994. With respect to such differences, provide the Subcommittee with a detailed description of how such differences are achieved?

* * *

The nicotine level in each of USTC's smokeless tobacco products is measured after the product has been packaged. USTC began taking these measurements in 1987 to comply with U.S. Department of Health and Human Services ("HHS") nicotine reporting requirements pursuant to the Comprehensive Smokeless Tobacco Health Education Act of 1986. As counsel for the Company informed staff, USTC does not have this information in a readily available form for the years 1980-1986. Average nicotine levels as a percentage of weight for the years 1987 through June 24, 1994, for each of USTC's smokeless tobacco products, are attached. (Attachment 5).

In addition, other analytical measurements are taken from time to time, including moisture, grain size, pesticide residue, pH, organic acids, and nicotine at various stages, e.g., after leaf processing, during aging, after cutting, and during curing as part of a broad profile of data to assist the Company in understanding the manufacturing process. USTC does not believe these measurements provide sufficient information to determine with

certainty at what point in the manufacturing process nicotine levels decline.

Differences in nicotine levels in USTC's smokeless tobacco products result primarily from the tobacco leaf blend. USTC's leaf blends are dictated by formulas that are decades old; Copenhagen, for example, is made using a formula dating back to 1822. Other factors, including moisture and flavoring levels, contribute to a decline in the nicotine level during the course of the manufacturing process. Even within an individual product containing a single formula and leaf blend, the nicotine levels vary from time to time (above or below the statistical mean) due to external factors such as different weather conditions affecting a particular crop year, or a particular growing region, and soil conditions. Indeed, the data underlying the statistical mean, collected by the Company since 1987 for HHS reporting purposes, indicates an overlap among the various products' respective nicotine levels, as shown by the data in Attachment 5 hereto.

8. Provide the Subcommittee with copies of all documents in the possession or under the control of your company relating to nicotine's addictiveness or lack of addictiveness, including all reports, memoranda, or other documents relating to research on nicotine's addictiveness.

* * *

Earlier conversations with staff indicated that the Subcommittee did not want the Company to produce published literature regarding this subject matter. Staff was advised of how the Company intended to proceed. During the inquiry conducted by counsel, described above in the Introduction, no responsive unpublished materials on the subject were found.

9. Does USTC utilize reconstituted tobacco in the manufacture of any of its oral tobacco products? If so, what is the nicotine concentration of reconstituted tobacco for each brand of oral tobacco manufactured by USTC for the period 1982-1994? Provide a description of how the nicotine concentration is achieved.

* * *

USTC does not utilize reconstituted tobacco in the manufacture of any of its smokeless tobacco products.

Your April 14 testimony states: "U.S. Tobacco does not . . . control the nicotine content of its tobacco products before, during or after the manufacturing process." In order to better understand this statement, respond to the following questions.

10a. In the manufacturing of smokeless tobacco does the nicotine level decline from the level present in the unprocessed leaf? If so, identify all points during the manufacturing process in which your company restores any nicotine lost during earlier steps in the manufacturing process. Also provide a detailed explanation for how nicotine levels in the unprocessed tobacco leaf used by your company are determined both before and after purchase.

10b. Describe each manufacturing process that adjusts, however incrementally, the nicotine level of your product.

* * *

In his testimony on April 14, 1994, Mr. Taddeo articulated the position of USTC as set forth in its statement of its current manufacturing practices: "U.S. Tobacco does not in any way manipulate or 'spike' the nicotine levels in its tobacco products. Nor does U.S. Tobacco take any action to control the nicotine content of its tobacco products before, during or after the manufacturing process." (Page 8). This statement was not intended to suggest that different blends of tobacco do not result in different nicotine levels.

Answer to Question 10a. USTC does not measure nicotine levels in unprocessed leaf, i.e., in tobacco leaf in the form it is received from the farmer, before or after purchase. As stated in USTC's response to Question 10b, below, the Company knows that nicotine levels decline during the manufacturing process.

USTC does not restore nicotine at any point during the manufacturing process. The only material used in the manufacture of USTC's smokeless tobacco products, other than the tobacco itself, which contains nicotine, is denatured alcohol which is purchased from a supplier as a carrying agent for the application of certain flavorings that do not dissolve in water. The denatured alcohol (SDA-4) used by USTC has been denatured by its manufacturer with small amounts of nicotine. The use of nicotine as a denaturant for alcohol, which is to be used in the processing and manufacturing of tobacco products, is specifically approved by the Bureau of Alcohol, Tobacco and Firearms. (See 27 CFR § 21.38). The amount of nicotine that might be contributed to a USTC smokeless tobacco product through the use of denatured alcohol in the manufacturing process is so minuscule as to be unmeasurable by standard laboratory methodologies.

Answer to Question 10b. No step in USTC's manufacturing process is taken for the purpose of adjusting the nicotine level of its smokeless tobacco products. It is known that nicotine levels decline as a result of the addition of water and other ingredients, and also to a minor degree due to evaporation. While USTC does from time to time make analytical measurements during the manufacturing process which may include nicotine levels, it does not believe it has sufficient information to determine with certainty at which point in the manufacturing process nicotine levels decline.

11. Although you acknowledge in your testimony the finding of the Surgeon General that smokeless tobacco was a cause of mouth cancer, you stated in response to a question from Mr. Synar that "Oral tobacco has not been established as a cause of oral cancer." Describe the nature of scientific evidence sufficient for your company to acknowledge that oral tobacco had been established as a cause of oral cancer?

* * *

In his testimony at the April 14, 1994 hearing, Mr. Taddeo expressed the Company's position that smokeless tobacco has not been established as a cause of oral cancer. This position, as to which the Subcommittee has asked for further explanation, is based upon the fact that, while a number of scientists believe that smokeless tobacco is a cause of oral cancer, others hold the view that it has not been scientifically established to be a cause of this disease.

Scientists on both sides of this controversy come from various scientific disciplines including epidemiology, toxicology, pathology and immunology. Their analyses and evaluations of the scientific evidence are influenced and shaped by their respective scientific disciplines. This is exemplified by the testimony and statements of the eminent scientists who appeared before, or submitted written statements to, this Subcommittee at the request of the Smokeless Tobacco Council on July 26, 1985. There is nothing that the Company can add to what these experts have stated regarding the "nature of the scientific evidence" or their opinions that the evidence does not warrant the conclusion that smokeless tobacco has been established as a cause of oral cancer.

12. USTC purchases denatured alcohol for the purpose of serving as "a carrying agent for the application of certain flavorings that do not dissolve in water." Identify the name and address of the company from whom denatured alcohol was purchased during the last five years.

* * *

During the last five years, USTC has purchased SDA-4, which is approved by the Bureau of Alcohol, Tobacco and Firearms (BATF) for use in the manufacture of tobacco products, from the Quantum Chemical Co., a division of U.S. Industrial, Inc., P.O. Box 429549, 11500 Northlake Drive, Cincinnati, Ohio, 45249.

13. You have testified that "The assertion that smokeless tobacco use can be addictive is without merit." Provide for the Record an explanation of the scientific basis for determining the addiction liability of a substance in humans. In answering this question, cite specific medical or scientific authorities upon which your explanation is based. With respect to nicotine, provide the Subcommittee with the specific criteria necessary for your company to acknowledge the addiction liability of nicotine containing oral tobacco.

* * *

In USTC's written statement submitted to the Subcommittee on April 14, 1994, the Company stated its view that "the assertion that smokeless tobacco use can be addictive is without merit." (Page 5). Mr. Taddeo also stated for the record his personal opinion in this regard: "I don't believe that nicotine or our products are addictive."

Question Thirteen seeks information regarding the "addiction liability" of a substance or nicotine. With respect to nicotine and the claim that smokeless tobacco use is "addictive," the Company's views are set forth in USTC's April 14, 1994 written statement, at pages five through seven.

14. You have testified that USTC does not want children or those under the age of 18 to use oral tobacco products. Does your company support the enforcement of laws prohibiting the sale of oral tobacco products to minors? If so, provide for the Subcommittee a description for (1) how enforcement of such laws should be promoted, (2) how retailer compliance can most effectively be monitored and (3) what, if any, penalty should be levied upon retailers selling oral tobacco products? With respect to each case, cite evidence that the proposed strategy recommended would produce verifiable and replicable effects in reducing illicit sales to youth.

15. Provide the Subcommittee with a State-by-State breakdown of annual expenditures by your company from 1982 - 1994 which were allocated to ensure adherence to minimum age of sale laws.

* * *

USTC has for a number of years participated in an "adults only" policy program sponsored by the smokeless tobacco industry to promote understanding that use of smokeless tobacco products is a custom reserved for adults.

The "adults only" policy program is a national (as opposed to state by state) comprehensive public education campaign with one central purpose: to repeatedly and consistently communicate our strict "adults only" policy to responsible adults nationwide. Our philosophy is that responsible adults are the people to whom youth look for guidance. Therefore, if these adults know and support our policy, we are making a difference.

Over the years, we have reached out to millions of adults -- parents, educators, coaches, retailers, public officials, and law enforcement officers whom we feel have a special influence

with youth. We have used public service announcements, such as "Smokeless Tobacco is Not for Kids" and "Some Things are Still for Adults Only" on television, in newspapers such as USA Today, and in magazines, to spread our message. We have communicated to adults through public addresses and specially prepared literature on the subject. We have distributed hundreds of thousands of signs, buttons and cards to retailers across the country detailing our "adults only" policy and asking them to help enforce our policy.

For example, the smokeless tobacco industry developed and implemented a public service announcement campaign "It's Our Responsibility", which emphasized the importance of parents helping to prepare their children to make adult decisions. Newspaper publication of this message reached more than 3 million readers.

Another campaign undertaken by the smokeless tobacco industry was entitled "4th R?" and asked teachers, coaches and other school employees to teach youth about responsible decision-making. This campaign was conducted through almost fifty education-related publications. The smokeless tobacco industry also has disseminated a publication entitled "A Continuing Commitment" to businesses, youth and civic organizations communicating our "adults only" policy.

We are encouraged by the fact that this comprehensive strategy is working. It is noteworthy that according to a recent HHS report, use of smokeless tobacco by males under eighteen years

of age is low, decreasing and very close to HHS's "target" or goal for the year 2000. The 1992 Healthy People 2000 Review states that the reported use of smokeless tobacco (defined as use on at least one occasion in the last thirty days) by 12-17 year-old males decreased from 6.6% in 1988 to 5.3% in 1991. Moreover, a survey published in October 1993 by the Substance Abuse and Mental Health Service Administration ("SAMHSA") reported that use of smokeless tobacco by 12-17 year-old males had further declined in 1992 to 4.8%, which is very close to the 4.0% "target" for the year 2000 set forth in the Healthy People 2000 Review. Furthermore, the reported use of smokeless tobacco by the total 12-17 year-old population (males and females) was only 2.6% in 1992, according to the SAMHSA survey.

Even though these trends are encouraging, USTC will continue its efforts to discourage the sale of smokeless tobacco products to minors. To date, the smokeless tobacco industry has spent $1.35 million to communicate its "adults only" program. A copy of our "adults only" booklet is included (Attachment 6).

USTC also subscribes to the smokeless tobacco industry code confirming its long standing policy that eighteen years of age is the minimum age of purchase for smokeless tobacco products. A copy of the Code is included (Attachment 7).

USTC, in conjunction with the smokeless tobacco industry, has actively supported the passage and enforcement of laws

prohibiting the sale of smokeless tobacco products to minors. In 1984, only twenty-two states had established eighteen as the minimum age of purchase for smokeless tobacco. Today each of the fifty states and the District of Columbia have established at least eighteen years of age as the minimum age to purchase smokeless tobacco.

Following passage in 1992 of the Alcohol, Drug Abuse and Mental Health Administration Reorganization Act ("ADAMHA"), the Smokeless Tobacco Council ("STC"), on behalf of USTC and other member companies, sent a personal letter to the Governor in each of the fifty states, an open letter to all state legislators by publication in Inside the Legislature, a publication formerly known as The Handbook of State Legislative Leaders, and a personal letter to each Member of Congress advising these public officials of the following:

- The 102nd Congress of the United States has approved legislation that establishes a national age of purchase of eighteen for tobacco products.
- The STC supports this law because it is consistent with the smokeless tobacco industry's long-standing "adults only" policy for the purchase of smokeless tobacco products.
- For many years the STC has supported minimum age of purchase laws for smokeless tobacco products.
- The STC has worked hard to convey its "adults only" policy to the public.

Finally, the letter observes that "the challenge is to ensure that states comply with and enforce the requirements of this new law", and requests that the respective Governors and legislators give the law "the priority it deserves." Representative copies of this letter are attached (Attachment 8).

The Tobacco Institute ("TI"), on behalf of its member companies which include USTC, also has initiated several national educational campaigns relating to the issue of tobacco use and youth and expended more than $15 million during the last ten years on programs to inform and educate youth, parents, retailers, and others that tobacco use is an adult custom. Three such campaigns are "Helping Youth Decide", "Tobacco: Helping Youth Say No" and "It's the Law".

"Helping Youth Decide" was a program designed to provide guidance on parent-child communications, including helping youth develop decision-making skills. The program included a written booklet entitled "Helping Youth Decide"; more than 700,000 copies of that publication were distributed.

Following widespread dissemination of "Helping Youth Decide", the TI undertook a national campaign known as "Tobacco: Helping Youth Say No." This campaign has included, among other things, the distribution of a booklet, public service announcements on television, and full page announcements in magazines. The booklet, entitled "Tobacco: Helping Youth Say No", is intended as

a guide to adults who work with youth. To date, more than 350,000 copies of this booklet have been distributed throughout the United States.

In addition to the distribution of this written material, the "Tobacco: Helping Youth Say No" campaign has included national media coverage, consisting of public service announcements on television. These public service announcements have been aired by more than 600 television stations across the country. This campaign also has included the placement of full-page statements in magazines such as People, TV Guide, and USA Weekend.

Beginning in 1990, and well before the enactment of ADAMHA legislation, the TI, again on behalf of its member companies including USTC, embarked upon a national campaign to help retailers observe and enforce the minimum age laws for the purchase of tobacco products. This national program, which includes signage in retail stores, educational material, and announcements in trade journals reaching a substantial number of retailers throughout the country, is called "It's the Law." The campaign has two objectives:

1. To continue to discourage those who are underage from purchasing tobacco products; and

2. To reaffirm that the tobacco industry does not want youth to use tobacco products -- and continues to take affirmative steps to reinforce this position.

The program's direct and aggressive communication with retailers is designed to encourage strict adherence to the minimum

age of purchase laws throughout the United States. To date, more than 2.4 million pieces of "It's the Law" materials have been distributed throughout the United States.

The three programs described above have reached millions of people nationwide and have communicated the message of tobacco product manufacturers very clearly -- tobacco use is an adult custom, for adults only.

Earmarking of State Tobacco Excise Taxes for Tobacco Youth Programs

In addition to the efforts of USTC and the tobacco industry generally, tobacco excise taxes have been used by federal and state governments to enforce laws, including the minimum age laws for the purchase of tobacco products.

Four states earmark revenue raised from excise taxes levied on cigarettes and/or other tobacco products ("OTP") to fund, among other things, programs relating to tobacco use and youth. The four states are California, Idaho, Massachusetts and Washington.

In 1988, California voters passed Proposition 99, which provided that twenty percent of the revenue raised by tobacco excise taxes be earmarked to the Health Education Account for the "prevention and reduction of tobacco use, primarily among children, through school and community health education programs." An example is Orange County, California's new program called "Teens

not Tobacco". According to a July 4, 1994 article in the L.A. Times, this program "trains teens to educate convenience store vendors about state law prohibiting the sale of tobacco to minors." For 1994-95, approximately $89.7 million from tobacco excise taxes will be appropriated for tobacco education and community programs. For 1995-96, almost $87.2 million has been appropriated by the legislature for such programs.

In 1994, the Idaho legislature raised the cigarette tax by ten cents per pack and the OTP rate an additional five percent of the wholesale price. Although the bill's legislative intent refers only to a reduction of tobacco use among young people as its purpose, the new revenues are earmarked to the Public School Income Fund for "substance abuse programs".

Massachusetts raised the state's cigarette and OTP tax rates in 1992 and earmarked the tax revenue. The fiscal year 1995 budget, subject to legislative appropriation, provides approximately $96 million for anti-tobacco advertising and school tobacco education programs. The 1994 budget was approximately $54 million.

In 1993, the Washington State legislature enacted legislation which provides that ninety percent of all fees collected for tobacco retailer and sampler licenses be placed in a Youth Tobacco Prevention Account. These funds are used to comply with ADAMHA enforcement and reporting requirements, but up to

seventy percent of the monies collected for the Youth Tobacco Prevention Account are to be given to local health departments and other community agencies "to develop and implement coordinated tobacco prevention strategies to prevent and reduce tobacco use by youth."

Other Tobacco Excise Taxes

Tobacco excise taxes collected by both the federal and state governments are used to help enforce the law, including the minimum age of purchase law in a particular state.

For more than 130 years, the United States has levied a tax on tobacco products. During this period, more that $138 billion in tobacco taxes have been collected by the United States government. For the year ending June 30, 1993, the federal government received more than $5.6 billion from excise taxes on tobacco products, an increase of $500 million from the 1992 total tobacco tax collected of $5.1 billion.

Since at least 1921-1922, states have imposed taxes on one or more forms of tobacco (cigarettes, cigars, pipe or smokeless tobacco). In 1937, at least twenty states taxed tobacco. By 1950-51, that number had almost doubled. In 1950-51, at least forty states and the District of Columbia levied excise taxes on tobacco products. In 1966, that number rose to forty-nine states and the

District of Columbia. By 1970, all fifty states and the District of Columbia taxed some form of tobacco.

The amount of excise taxes collected by the states is set forth below:

Year ending June 30:

1993	$ 6.270 billion
1992	$ 6.131 billion
1991	$ 5.958 billion
1990	$ 5.594 billion
1989	$ 5.114 billion
1921-1988	$ 92.186 billion
TOTAL:	$121.253 billion

Source: The Tax Burden of Tobacco, The Tobacco Institute, Inc., 1993.

ASSIST Program

In 1991, a seven-year project entitled "American Stop Smoking Intervention Study for Cancer Prevention" (known as "ASSIST") was undertaken with $135 million of public and private funds for activities to be conducted in seventeen states. According to a New York Times report dated November 10, 1993, ASSIST's primary focus is as follows:

> Major emphasis will also be placed on stemming illegal sales of tobacco products to minors. In ASSIST communities, teenage undercover agents will monitor compliance with the law by acting as buyers, and states that fail to enforce their laws will lose Federal funds.

ASSIST is expected to reach ninety-one million people, or one third of the United States population. A list of the seventeen

ASSIST states is set forth below, along with the amount of money each state will receive for participating in this program.

In connection with the ASSIST program, the Centers for Disease Control and Prevention ("CDC") made available $3 million in grant money to those states that did not receive ASSIST funds. In July 1994, CDC announced that an additional $1 million would be available to non-ASSIST states.

States Participating in ASSIST

State	Lead Agency	Amount of Award
Colorado	Colorado Department of Health	$ 6.9 million
Indiana	Indiana State Board of Health	$ 7.3 million
Maine	Maine Department of Human Services	$ 4.6 million
Massachusetts	Massachusetts Health Research Institute	$ 7.4 million
Michigan	Michigan Department of Health	$10.8 million
Minnesota	Minnesota Department of Health	$ 6.3 million
Missouri	Missouri Department of Health	$ 6.1 million
New Jersey	New Jersey State Department of Health	$ 7.5 million
New Mexico	New Mexico Department of Health	$ 4.9 million
New York	Health Research, Inc. (New York State Department of Health)	$11.3 million
North Carolina	North Carolina Department of Health	$ 8.4 million
Rhode Island	Rhode Island Department of Health	$ 4.9 million
South Carolina	South Carolina Department of Health	$ 5.4 million
Virginia	Virginia Department of Health	$ 6.0 million
Washington	Washington Department of Health	$ 7.3 million
West Virginia	West Virginia Department of Health	$ 4.8 million
Wisconsin	Wisconsin Division of Health	$ 9.2 million

Foundations

In recent years, foundations have directed tens of millions of dollars into programs that focus on the issue of tobacco and youth. Recently, for example, The Robert Wood Johnson Foundation announced a $10 million grant to 19 states "to promote policies that prevent the sale of tobacco to minors...." A list of some foundation grants that relate to tobacco and youth is attached (Attachment 9).

Federal Grants

For years, the federal government has made millions of dollars available to both the public and private sectors for programs related to tobacco and youth. An example of the type and scope of grants made available by the federal government is reflected in the attached list of some 1994 grants. (Attachment 10).

16. P.L. 102-321 required States to enact and enforce minimum age of sale laws for tobacco products. Provide information on the amount and purpose of expenditures by your company, directly or indirectly, regarding state regulation of tobacco sales for representation before state legislatures for each year between 1989-1994.

* * *

Like many corporations, USTC and its sister companies monitor through various trade associations, state legislative consultants, and employees, state legislation affecting their ability to conduct business. Tax, environmental, and employment legislation, and regulatory proposals affecting the sale and distribution of tobacco products are examples.

Currently there are six USTC employees working on smokeless tobacco legislative matters at the state level. From time to time USTC also has retained outside consultants to assist in this effort and has expended the following for these consultants for the years 1989-1994:

1989	$ 53,374.
1990	$ 23,609.
1991	$ 79,687.
1992	$ 7,750.
1993	$ 55,470.
1994	$ 7,000.

In addition, the STC, of which USTC is a member, has expended the following for state legislative consultants for the years 1989-1994:

1989	$1,148,500.	
1990	$1,326,200.	
1991	$1,457,416.	
1992	$1,563,260.	
1993	$1,695,060.	
1994	$1,799,885.	estimated

17. Provide for the Subcommittee an estimate by year of the total sales for each of your oral tobacco products resulting from underaged purchases? Provide this information for the period 1989-1994.

* * *

USTC has long held the view that smokeless tobacco products should be used only by adults. The Company has adopted policies to ensure the advertising and sampling of its smokeless tobacco products are not directed at individuals under the age of eighteen.

USTC has no information apart from publicly available material regarding the use of smokeless tobacco products by minors. The following research concludes that family and friends are the primary influences on the decision to begin using various products, including smokeless tobacco:

Marty, P.J., et al. Patterns of Smokeless Tobacco Use in a Population of High School Students. Am. Jnl. Pub. Hlth. 76(2): 190-192; 1986.

Williams, T., et al. Smokeless Tobacco Use Among Rural High School Students in Arkansas. Jnl. Sch. Hlth. 56 (7): 282-285; 1986.

Guggenheimer, J., et al. Changing Trends of Tobacco Use in a Teenage Population in Western Pennsylvania. Am. Jnl. Pub. Hlth. 76(2): 196-197; 1986.

18. Provide for each year since 1980, advertising and promotional expenditures for the following brands of oral snuff: Happy Days; Skoal Bandits; Skoal Long-Cut; Skoal; Copenhagen. In providing this information use the Federal Trade Commission's categories of advertising and promotional expenditures.

* * *

Appended to this memorandum are copies of the information submitted to the Federal Trade Commission ("FTC"), pursuant to that agency's Section 6(b) Orders to File Special Reports.[5] (Attachment 11). Pursuant to Section 6(f) of the FTC Act, this information has been treated by the FTC as confidential (See Attachment 12). The Company also considers this "confidential information" pursuant to Paragraph 5 of the Uniform Procedures for Tobacco Documents, Subcommittee on Health and the Environment, September 30, 1994, and has stamped the material accordingly.

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[5] In discussions with the Subcommittee staff, counsel for the Company indicated that the information responding to Question 18 was not readily available for years prior to 1986, since prior to that time the FTC did not require reporting of such information. Consequently, the staff agreed to accept submission of the Special Reports as required by the FTC for the years 1986-1993.

19. Provide for the Subcommittee information on the relative ages of oral tobacco users for each of USTC oral tobacco products for each of the years 1982-1994.

* * *

In 1986, and again in 1992 and 1993, the Company conducted market research which contained information on the age demographics of consumers of its smokeless tobacco products. The Company is producing this market research. (Attachment 13).

The Company previously has submitted market research reports in response to Question 6 that contain information on the age demographics of consumers of the Company's smokeless tobacco products. (See Attachment 4.)

According to the Company's most recent information, the age demographics of consumers of the Company's smokeless tobacco products are as follows:

USTC Smokeless Tobacco Product	Average Age
Copenhagen	34.91
Skoal Fine Cut	36.12
Skoal Long Cut	36.95
Skoal Bandits	37.51

The Company considers the market research documents submitted in response to Questions 6 and 19, as well as the age demographics set forth above, to be "confidential information" pursuant to Paragraph 5 of the Uniform Procedures for Tobacco Documents, Subcommittee on Health and the Environment, September 30, 1994, and has stamped the material accordingly.

20. Green tobacco sickness is said to be a form of nicotine poisoning which occurs when field workers touch wet tobacco. Enclosed is a copy of articles from the Journal of the American Medical Association and the Centers for Disease Control's Morbidity and Mortality Weekly Report which describe the illness. Describe what, if any, steps your company has taken during the period 1982 - 1994 to reduce the risks of this disease among tobacco field workers. During this same period has your company financed research into preventing or improving available treatment for this illness? If so, describe the nature of such research and the relevant outcomes.

* * *

USTC does not grow tobacco itself for use in its smokeless tobacco products, but instead purchases tobacco leaf both at open auction and from independent farmers who are members of various tobacco leaf associations. Tobacco field workers are employed by the tobacco farm owners, and are not under the supervision or control of USTC.

While Question 20 references the 1982-1994 timeframe with regard to what has been characterized as "green tobacco sickness" ("GTS"), the materials appended to Chairman Waxman's letter state that "[b]efore 1992, no cases of GTS had been reported to Kentucky public health agencies."[6] Kentucky and Tennessee are the states where the tobacco used in USTC's smokeless tobacco products is cultivated. One cited article mentions that the incidence of GTS among Kentucky tobacco harvesters is not currently known.[7] Other materials appended to Chairman Waxman's letter suggest that GTS

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[6] U.S. Public Health Service, Centers for Disease Control. Green Tobacco Sickness in Tobacco Harvesters - Kentucky, 1992. Morbidity and Mortality Weekly Report 42 (13): 237-239 at p. 238; April 9, 1993.

[7] Id. at 239.

occurs with some frequency in North Carolina,[8] which is not a source for the type of tobacco used by USTC. Therefore, USTC has not directly financed research into GTS.

The apparent disparity in the incidence of GTS in North Carolina and Kentucky may stem from the difference in harvesting practices of the dark fired and dark air-cured tobaccos used in USTC smokeless tobacco products, and the flue-cured tobacco used in other products. Flue-cured tobacco is harvested by picking the leaves off the plant. Apparently, this is done sometimes when the leaves are wet from dew or rainfall. Dark tobaccos are not harvested while wet; the plants are harvested when dry because in this condition the stalks can be cut more easily.

Since 1992, GTS has been monitored actively by the National Institute for Occupational Safety and Health ("NIOSH") through a national surveillance program in rural communities investigating all agriculture-related illnesses and injuries that occur among farmers and family members. NIOSH is working closely with various state health agencies to disseminate information and educate farm owners and workers -- through state cooperative extension services and newspapers -- of the steps they can take to prevent occupational dermal exposures. These steps include: (1) use of personal protective equipment, such as gloves and plastic outerwear; (2) implementation of safe work practices such as flexible harvest schedules to take wet conditions into account; and

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[8] Gellenbach, S.H., et al. Green Tobacco Sickness. Jnl. Am. Med. Assn. 229 (14): 1880-1883 at p. 1880; 1974.

(3) worker education and training. We understand that the CDC has a monitoring program. Further, the organization known as the Occupational Health Nurses in Agricultural Communities sponsors a "glove use" program. The published literature suggests that education and prevention appear to be the most effective way of dealing with GTS.[9]

21. In the past representatives of your company have expressed the position that advertising in the U.S. is not directed at individuals under the age of 18. Is this also your company's policy in advertising and promoting oral tobacco sales in Asia, South America and Eastern Europe?

* * *

USTC has long held the view that smokeless tobacco products should be used by adults only. Accordingly, the Company subscribes to and requires its employees to sign an "Advertising and Sampling Code" (the "Sampling Code") to ensure that the advertising and sampling of its smokeless tobacco products are not directed at individuals under the age of eighteen. (See Attachment 14). The USTC Sampling Code is consistent with the code published by the Smokeless Tobacco Council, for the industry. (See Attachment 7).

These policies also govern the sampling activities of USTC's sister company, United States Tobacco International, in overseas markets. Distributors of the Company's smokeless tobacco products in foreign countries sign a version of the Sampling Code. Where appropriate, the Sampling Code is adapted in foreign countries to comply with local laws, if the laws are more restrictive.

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[9] See, e.g., Hipke, M.E., Green Tobacco Sickness. So. Med Jnl. 86 (9): 989-992; 1993.

22. Provide the Subcommittee with a definition for the term "tobacco satisfaction".

* * *

Consumers define "satisfaction" according to their own subjective perspectives, regardless of the product involved. The packaging and advertising for many consumer goods and services speak in terms of "satisfaction" or "satisfaction guaranteed."

The adults who choose to use smokeless tobacco products purchase brands they find satisfying according to their individual preferences, including flavor, cut of tobacco, form, ease of use, and packaging. In light of these obviously subjective preferences, it would appear that each smokeless tobacco consumer could define "tobacco satisfaction" differently. USTC first began using the slogans "Copenhagen It Satisfies" and "It Satisfies" in 1939. (See Attachment 15). Like many advertising slogans, the terms doubtless mean different things to different people.

23. You state in your testimony that USTC does not employ a graduation strategy in the marketing of oral tobacco products and have characterized the strategy as a "fanciful concept . . . . created by plaintiff's counsel in the 1986 Marsee litigation." It is the Subcommittee's understanding that a number of documents concerning nicotine and the so-called "graduation strategy" were offered but not admitted as evidence. Submit to the Subcommittee all documents offered to the Court in the Marsee litigation but not admitted into evidence dealing with the issue of nicotine and/or the graduation strategy.

* * *

The Subcommittee has requested in Question 23 certain documents offered by the plaintiff but ruled irrelevant and inadmissible by the Court in the 1986 Marsee case. In light of the Court's ruling, the Company has concerns about the production of these documents to the Subcommittee. These concerns include whether the confidentiality of Company documents can be maintained. We note that a senior Subcommittee staff member is scheduled to appear at the December 2-4, 1994, conference of the Tobacco Products Liability Project to "answer questions about congressional investigations."

As Chairman Waxman has recognized, there are "special and unique circumstances" surrounding the current inquiry, "including the involvement of the tobacco companies in extensive product liability litigation." Given our concerns about leaks and the promotion of misinformation, the Company has decided to defer the production of these documents at this time. The Company is willing, however, to discuss this matter further with the Subcommittee.

The Company understands today that, in the early 1980s, there were discussions among some at USTC about a "graduation process", "hypothesis", or "theory." While the term "graduation process" apparently meant different things to different people, the theory seems to have been an attempt by some to provide a shorthand explanation for consumer behavior in switching between brands of smokeless tobacco, including between the Company's own brands.

The "fanciful concept" referenced in the Company's April 14, 1994, statement was to allegations by Dr. Jack Henningfield that "graduation process" meant the Company employed a deliberate marketing strategy to entice consumers with low-nicotine products and then move them through so-called nicotine "addiction" to products with higher levels of nicotine. The Company never had such a strategy.

As best as the Company can now determine, the term "graduation process" as used in the early 1980s (i) did not relate to increasing levels of nicotine and pH; (ii) did not drive the Company's marketing strategies; and (iii) is contradicted by consumer behavior in the marketplace. Indeed, consumer demographic data, including the information produced to the Subcommittee in response to Question 6 and Question 19, demonstrate that there is significant brand loyalty among smokeless tobacco consumers, and that many -- if not most -- stay with the brand they first choose. Moreover, the data demonstrate that whatever brand switching occurs does not readily fall within any pattern that could be viewed as consistent with the notion of a pre-ordained "graduation process."

In addition to individual taste preferences, there are many social and other factors that cause smokeless tobacco consumers to choose their respective brands. The Company's current view on these issues was set forth in its statement of April 14, 1994: "[s]mokeless tobacco consumers remain loyal to a single brand or switch among a variety of brands according to their taste preferences, cut of tobacco, form and packaging." (See p.17).

(Subcommittee note: Attachments described below are retained in subcommittee files.)

1. Letter dated May 19, 1994, from the Honorable Henry A. Waxman, Chairman, House Subcommittee on Health and the Environment to Joseph R. Taddeo, President, United States Tobacco Company.

2. Letter dated April 22, 1994, from Joseph R. Taddeo, President, United States Tobacco Company, to the Honorable Henry A. Waxman, Chairman, House Subcommittee on Health and the Environment.

3. Final reports regarding third-party animal laboratory testing. (Question 3; Bates Nos. 03001-03018).

4. United States Tobacco Company market research reports (Question 6; Bates Nos. 60001-61034).

5. Nicotine levels for 1987 through June 24, 1994, for each of United States Tobacco Company's finished smokeless tobacco products, as a percentage of weight. (Question 7; Bates Nos. 07001-07002).

6. The Smokeless Tobacco Council Inc.'s Adults Only policy program. (Questions 14 and 15; Bates Nos. 14001 - 14016).

7. The Code of the Smokeless Tobacco Industry. (Questions 14 and 15; Bates No. 14017).

8. Smokeless Tobacco Council, Inc. letters to legislators regarding minimum age of purchase legislation approved by the 102nd Congress. (Questions 14 and 15; Bates Nos. 14018 - 14020).

9. Foundation Grants Relating to Tobacco and Youth. (Questions 14 and 15; Bates Nos. 14021 - 14028).

10. 1994 Federal Grants Relating to Tobacco and Youth. (Questions 14 and 15; Bates Nos. 14029 - 14032).

11. United States Tobacco Company Special Reports filed pursuant to Federal Trade Commission Orders dated May 19, 1987; May 19, 1988; June 7, 1990; March 10, 1992; and April 4, 1994 covering the years 1986 - 1993. (Question 18; Bates Nos. 18001 - 18211).

12. Letter from C. Lee Peeler, Associate Director, Federal Trade Commission, to Martha J. Waldheger, Senior Corporate Counsel, United States Tobacco Company, dated October 1, 1993. (Question 18; Bates No. 18212).

13. United States Tobacco Company market research including age demographics. (Question 19; Bates Nos. 19001 - 19321).

14. United States Tobacco Company Advertising and Sampling Code for Smokeless Tobacco Products. (Question 21; Bates Nos. 21001 - 21002).

15. United States Tobacco Company registered trademarks. (Question 22; Bates Nos. 22001 - 22003).

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